

Currently Cleared CBER 510(k) Clearances
As of September 04, 2012
Sorted by Applicant Name

BK980025 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:Plasma Center Module - 1.0
Cleared Date: 18-MAY-1999
Cleared Under Fifth Dimension Information
Systems

BK990022 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:Donor Management System - 1.0.0
Cleared Date: 10-SEP-1999
Cleared Under Fifth Dimension Information
Systems

BK000026 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:P2K Plasma Center Module 2000 -
1.0
Cleared Date: 22-JUN-2000
Cleared Under Fifth Dimension Information
Systems

BK020058 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:LOGIC - 1.0
Cleared Date: 03-FEB-2003
Cleared Under Fifth Dimension Information
Systems

BK040040 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:LOGIC - 2.0
Cleared Date: 06-OCT-2004
Cleared Under Fifth Dimension Information
Systems

BK050060 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:E-Interview (eQue) - 1.0.0
Cleared Date: 24-MAY-2006
Cleared Under Fifth Dimension Information
Systems

BK060051 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name:HaemoConnect (eLynx) - 1.0.0

Cleared Date: 06-MAR-2008

BK070011 ABSORBER AB
Drottninggatan 33
Stockholm, Sweden SE-103 95
Trade Name:XM-ONE Transplantation Cross Match
Cleared Date: 29-JUL-2008

BK960027 ADAC HealthCare Information System
5 Greenway Plaza
Suite 1900
Houston, TX 77046
Trade Name:ADAC Blood Bank System
Cleared Date: 12-AUG-1998

BK050005 ALBA Bioscience
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United
Kingdom EH17 7QT
Trade Name:Quant-Rho FITC Anti-D for Fetal
Cell Assay
Cleared Date: 27-SEP-2005

BK070033 ALBA Bioscience
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United
Kingdom EH17 7QT
Trade Name:AlbaQ-Chek Simulated Whole Blood
Controls
Cleared Date: 27-JUL-2007

BK080027 ALBA Bioscience
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United
Kingdom EH17 7QT
Trade Name:ALBCheck - BGS Reagent Control
for Anti-D
Cleared Date: 29-JUL-2008

BK080051 ALBA Bioscience
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United
Kingdom EH17 7QT
Trade Name:FETALSCREEN
Cleared Date: 08-APR-2009

BK090030 ALBA Bioscience
21 Ellen's Glen Road
Liberton, Edinburgh

EH17 7QT
Scotland, UNITED KINGDOM, United
Kingdom EH17 7QT
Trade Name:ALBACheck- BGS Whole Blood
Controls-SP
Cleared Date: 14-JUN-2010

BK100005 ALBA Bioscience
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United
Kingdom EH17 7QT
Trade Name:ALBAcyte IgG Sensitized Red Blood
Cells
Cleared Date: 26-AUG-2010

BK870009 ARK-Bio-Medical Canada Corp.
#671 Rustico Road
Winsloe, Canada C1E 1Z2
Trade Name:WesLabs Model 601
Cleared Date: 15-NOV-1989
Cleared Under Rush Enterprises, Inc.

BK950048 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name:Abbott Apheresis Results Tracking
System/AARTS
Cleared Date: 24-JUN-1998

BK950052 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name:Abbott DMS II Data Management
System
Cleared Date: 12-AUG-1998

BK970042 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name:ABBOTT PRISM System
Cleared Date: 14-JUN-1999

BK010036 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name:ABBOTT PRISM Retest Server - 1.0
Cleared Date: 17-JUL-2002

BK060028 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name:Abbott PRISM Retest Server
Cleared Date: 07-JUN-2006

BK080015 Abbott Laboratories

100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name:ABBOTT PRISM Director V2.0
Cleared Date: 24-APR-2008

BK810599 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name:Dade Rh Control Reagent
Cleared Date: 31-MAR-1981

BK820004 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name:Trans-Type Reagents
Cleared Date: 29-OCT-1982

BK830001 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name:Polycation Potentiator System
Cleared Date: 06-MAY-1983

BK860038 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name:Data-Fi Thrombin Reagent
Cleared Date: 16-JAN-1987

BK890018 Ackrad Laboratories

70 Jackson Dr.
Cranford, NJ 07016
Trade Name:Ackrad Blood Warming Assembly
Cleared Date: 21-SEP-1990

BK960071 AcroMetrix Corporation

6058 Egret Court
Benicia, CA 94510
Trade Name:ViroSure Multi-Marker
Cleared Date: 11-FEB-1998

BK040060 AcroMetrix Corporation

6058 Egret Court
Benicia, CA 94510
Trade Name:VeriSure Pro External Quality
Controls
Cleared Date: 03-MAY-2005

BK050061 AcroMetrix Corporation

6058 Egret Court
Benicia, CA 94510
Trade Name:VeriSure Pro WNV RNA Negative
External Quality Control
VeriSure Pro WNV RNA Positive
External Quality Control
VeriSure Pro West Nile Virus (WNV)
RNA External Quality Controls:
Cleared Date: 21-DEC-2005

BK060064 AcroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
Trade Name:VeriSure Pro HBV DNA External
Quality Control
Cleared Date: 08-FEB-2007

BK960002 Activated Cell Therapy Inc.
291 North Bernardo Avenue
Mountain View, CA 94043
Trade Name:ACT Buoyant Density Solution
Cleared Date: 12-AUG-1996

BK940054 Alpha Scientific Corporation
P.O. Box 725
Southeastern, PA 19399
Trade Name:SEG-Safe (TM)
Cleared Date: 15-MAR-1995

BK950014 Alpha Scientific Corporation
P.O. Box 725
Southeastern, PA 19399
Trade Name:SEG-SAFE
Cleared Date: 31-MAR-1995

BK860014 Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, CA 90032
Trade Name:JMS Double Blood Collection Pack
Cleared Date: 04-JUN-1986

BK870004 Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, CA 90032
Trade Name:Plasma Transfer Pack
Cleared Date: 11-MAR-1987

BK950044 Alpha Therapeutic Corporation
13111 Temple Avenue
City of Industry, CA 91746
Trade Name:Transfer Device
Cleared Date: 18-OCT-1995

BK950021 Alton Dean Medical, Inc.
1547 West 2290 South
Woods Cross, UT 84087
Trade Name:Alton Dean Model FW-437
Cleared Date: 15-MAY-1995

BK960030 American Blood Resources Association
PO Box 669
Annapolis, MD 21404
Trade Name:National Donor Deferral Registry
Cleared Date: 20-MAR-1997

BK010012 American Blood Resources Association

147 Old Solomons Island Rd.
Annapolis, MD 21401
Trade Name:National Donor Deferral Registry
(NDDR) - 1.0
Cleared Date: 06-SEP-2001

BK960040 American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name:NBCS 1.1
Cleared Date: 28-FEB-1997

BK090021 American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name:Control Cells
Cleared Date: 24-JUN-2009

BK820016 American Red Cross Blood Services
15601 Crabbs Branch Way
Rockville, MD 20855
Trade Name:ARC HLA Extended Trays
ARC HLA Trays
Cleared Date: 01-JUN-1983

BK840015 American Red Cross Blood Services
15601 Crabbs Branch Way
Rockville, MD 20855
Trade Name:Bovine Albumin 3%
Cleared Date: 25-OCT-1984

BK880021 American Red Cross Blood Services
15601 Crabbs Branch Way
Rockville, MD 20855
Trade Name:Frozen-Dried Bromelain
Cleared Date: 21-DEC-1988

BK020032 American Red Cross Blood Services
Quality and Regulatory Affairs
1616 Fort Myer Drive
Arlington, VA 22209
Trade Name:NGTL Automation System (NAS) -
5.2.0
Cleared Date: 20-MAR-2003

BK850010 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Rh-Hr Control
Cleared Date: 27-DEC-1985

BK850023 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec CM-Tec Control

Cleared Date: 30-DEC-1985

BK860002 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Bovine Albumin 22%
Cleared Date: 03-MAR-1986

BK860003 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Bovine Albumin 30%
Cleared Date: 03-MAR-1986

BK860008 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec Anti-A1 Lectin
Cleared Date: 16-JUN-1986

BK860009 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec Anti-N Lectin
Cleared Date: 18-SEP-1987

BK860010 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec PS
Cleared Date: 16-DEC-1986

BK860020 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec R-E-S System
Cleared Date: 25-FEB-1987

BK860021 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec Coombs Control Cells
Cleared Date: 26-AUG-1986

BK860026 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec Anti-H Lectin
Cleared Date: 27-JAN-1987

BK860036 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name:Model Series, Mini & BB
Cleared Date: 24-FEB-1987

BK870020 Amtec Diagnostics International Inc.

1107 IH-45 South
Conroe, TX 77305
Trade Name:Amtec Ficin System
Cleared Date: 02-FEB-1988

BK010024 Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404
Trade Name:ViroSeq HIV-1 Genotyping System
Cleared Date: 10-DEC-2002

BK030005 Applied Biosystems
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name:ViroSeq HIV-1 Genotyping System
Cleared Date: 29-JAN-2003

BK010031 Applied Science, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name:Hemoflow Model 400 with Data
Scanner
Cleared Date: 23-JAN-2002

BK990011 Applied Sciences, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name:HemoFlow Donor Monitor
Cleared Date: 16-JUL-1999

BK990019 Applied Sciences, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name:HemoFlow Donor Monitor and Mixer
Cleared Date: 05-OCT-1999

BK020031 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name:ASI TPHA Test
Cleared Date: 30-JAN-2003

BK940022 Arrow International, Inc.
P.O.Box 12888 3000 Bernville Road
Reading, PA 19612
Trade Name:Arrow Qwik-1 TM Blood and Fluid
Administration Set
Cleared Date: 14-JUL-1994

BK070069 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name:Arthrex Double Syringe (ACP,
Autologous Conditioned Plasma)
System
Cleared Date: 12-DEC-2008

BK910017 Assoc. of Cape Cod
P.O. Box 224
Woods Hole, MA 02543
Trade Name:Control Standard
Endotoxin/Pepyrogeneration Valid.
Cleared Date: 21-OCT-1991

BK940032 Augustine Medical, Inc.
10393 West 70 th Street
Eden Prairie, MN 55344
Trade Name:Bair Hugger Patient Warming Device
Cleared Date: 29-SEP-1994

BK930027 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:Accurun 1
Cleared Date: 25-OCT-1994
Cleared Under Boston Biomedica, Inc.

BK970004 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN155
Cleared Date: 23-APR-1999
Cleared Under Boston Biomedica, Inc.

BK990032 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:Accurun 106 HIV-1 Antigen
Cleared Date: 20-JAN-2000
Cleared Under Boston Biomedica, Inc.

BK010038 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:Accurun 1 Multimarker Negative
Control
Cleared Date: 18-DEC-2001
Cleared Under Boston Biomedica, Inc.

BK040006 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN 315 HIV-1 RNA Positive
Control
Cleared Date: 12-OCT-2004
Cleared Under Boston Biomedica, Inc.

BK040016 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN 305 HCV RNA Positive
Quality Control
Cleared Date: 17-DEC-2004
Cleared Under Boston Biomedica, Inc.

BK040064 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN 345 HIV-1 RNA, HCV RNA,
HBV DNA Positive Quality Control
Series 150
Cleared Date: 29-OCT-2004
Cleared Under Boston Biomedica, Inc.

BK040067 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN 803 Nucleic Acid Negative
Quality Control (HIV, HCV, HBV)
Cleared Date: 19-NOV-2004
Cleared Under Boston Biomedica, Inc.

BK060022 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN 365 West Nile Virus RNA
Positive Quality Control
Cleared Date: 12-JUN-2006

BK060030 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name:ACCURUN 804 Nucleic Acid Negative
Quality Control (HIV, HCV, HBV,
WNV)
Cleared Date: 18-AUG-2006

BK100037 BBK Technology LLC
2910 E Highland Ave
Phoenix, AZ 85016
Trade Name:RC-AID
Cleared Date: 13-SEP-2010

BK030027 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name:BD IMAGN Microvolume Fluorimeter
and BD IMAGN rWBC Assay Kit
Cleared Date: 10-JUL-2003

BK050062 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name:BD HLA-B27 kit
Cleared Date: 27-OCT-2005

BK050073 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name:BD HLA-B27 System
Cleared Date: 16-FEB-2006

BK110037 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name:BD Stem Cell Enumeration Kit
Cleared Date: 19-OCT-2011

BK980011 BECTON DICKINSON VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Trade Name:VACUTAINER Brand PLUS (Plastic)
Blood Collection Tube with EDTA
Anticoagulant
Cleared Date: 07-JUN-1999

BK820008 BMT Incorporated
7315 Hazeltine Boulevard
Excelsior, MN 55331
Trade Name:BMT Model 24 Bloodmixer
Cleared Date: 22-OCT-1982

BK940031 Bard Radiology
10115 Highway 142
Covington, GA 30209
Trade Name:True-Pulse Infusion Catheter
Cleared Date: 27-APR-1995

BK100063 Barkey GmbH & Co KG
Gewerbestrasse 8
D-33818 Leopoldshoehe
, Leopoldshoehe Germany 33818
Trade Name:plasmatherm
Cleared Date: 17-NOV-2011

BK900010 Baxter Healthcare Corporation
1851 Delaware Parkway
Miami, FL 33152
Trade Name:Dade Chemically Modified Control
Reagent
Cleared Date: 21-SEP-1990

BK920025 Baxter Healthcare Corporation
1 Baxter Pkwy.
Deerfield, IL 60015
Trade Name:Dade Fetal-Cyte Screening Kit
Cleared Date: 05-AUG-1993

BK940062 Baxter Healthcare Corporation
1 Baxter Pkwy.
Deerfield, IL 60015
Trade Name:Cryocyte TM
Cleared Date: 27-DEC-1994

BK950049 Baxter Healthcare Corporation
9 Parker
Irvine, CA 92618
Trade Name:Cryocyte Freezing Container

Cleared Date: 14-FEB-1996

- BK960010 Baxter Healthcare Corporation
9 Parker
Irvine, CA 92618
Trade Name:Cell Wash Set
Cleared Date: 22-MAY-1996
- BK020002 Baxter Healthcare Corporation
550 North Brand Blvd.
Glendale, CA 91203
Trade Name:Serology SQL LIMS - 1.0
Cleared Date: 07-AUG-2002
- BK020059 Baxter Healthcare Corporation
25212 West ILL Route 120
RoundLake, IL 60073
Trade Name:ALYX Component Collection System
Cleared Date: 23-JAN-2003
- BK030052 Bayer HealthCare Diagnostics Division
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 08-OCT-2003
- BK040052 Bayer HealthCare Diagnostics Division
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 15-OCT-2004
- BK050035 Bayer HealthCare Diagnostics Division
P.O. Box 2466
Berkeley, CA 94702-5828
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 20-SEP-2005
- BK010044 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name:stemONE System for EPICS XL/ XL-
MCL Flow Cytometry Systems
Cleared Date: 20-MAY-2002
- BK020063 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name:LeukoSure Enumeration Kit with
Leuko-Trol RBC Control Cells and
Leuko Trol Platelet Control Cells
Cleared Date: 03-FEB-2003

BK040032 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name:Stem-Kit Reagents
Cleared Date: 05-MAY-2004

BK040055 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name:stemCXP System for the FC 500 with
CXP Software
Cleared Date: 16-SEP-2004

BK930010 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name:HLA-B27 Screening Systems
Cleared Date: 09-SEP-1993

BK940015 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name:The HLA-B27 System
Cleared Date: 24-OCT-1994

BK960087 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name:ProCount Progenitor Cell
Enumeration Kit
Cleared Date: 04-JUN-1998

BK970038 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name:Procount Software
Cleared Date: 04-FEB-1999

BK970046 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name:LeucoCOUNT Reagent
Cleared Date: 14-AUG-1998

BK950068 Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name:CMV Scan Card Test
Cleared Date: 22-DEC-1995

BK040030 Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name:BD Vacutainer Plus Plastic Serum

Tubes with Clot Activator
Cleared Date: 05-MAY-2004

BK050036 Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name:BD Vacutainer Plus K2EDTA Tubes
BD Vacutainer Plus Serum Tubes
BD Vacutainer SST Glass Tubes
BD Vacutainer SST II Advance Tubes
BD Vacutainer SST Plus Tubes
Cleared Date: 24-FEB-2006

BK060046 Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name:Bd.id Patient Identification
System for Transfusion Management
- V7.00
Cleared Date: 13-FEB-2007

BK960001 Behring Diagnostics
175 University Avenue
Westwood, MA 02090
Trade Name:OPUS CMV
Cleared Date: 09-OCT-1996

BK970035 BioAccess, Inc.
8400 Cedar Street
Silver Spring, MD 20910
Trade Name:Bioaccess Marrow Collection System
Cleared Date: 23-DEC-1998

BK000046 BioE, Inc.
4280 Centerville Road
St. Paul, MN 55127
Trade Name:FluoroTrol Control Kits
Cleared Date: 02-APR-2001
Cleared Under BioErgonomics, Inc.

BK070067 BioE, Inc.
4280 Centerville Road
St. Paul, MN 55127
Trade Name:PrepaCyte(R)-CB Processing System
Cleared Date: 17-DEC-2008

BK050029 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name:Donor Information System (DIS) -
3.1
Cleared Date: 07-JUL-2005

BK060017 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name:Donor Information System (DIS) -

3.2

Cleared Date: 09-MAY-2006

BK080016 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name:Donor Information System - v3.3
Cleared Date: 02-JUL-2008

BK090001 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name:Donor Information System (DIS) -
version 4.0
Cleared Date: 18-AUG-2009

BK100021 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name:Donor Information System (DIS)
Cleared Date: 18-JUN-2010

BK970017 BioMerieux
1022 Hingham Street
Rockland, MA 02370
Trade Name:HLA-DR Oligo Detection Kit
Cleared Date: 28-MAY-1998

BK860005 BioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name:Plasma Collection Bag
Cleared Date: 19-DEC-1986

BK870019 BioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name:Quik-Chek
Cleared Date: 19-MAY-1988

BK880003 BioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name:Therapeutic Plasmapheresis
Collection Bag
Cleared Date: 11-MAR-1988

BK920037 BioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name:PEG+
Cleared Date: 21-OCT-1993

BK960026 BioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name:Status Symbol TM II System

Software
Cleared Date: 16-MAR-1999
Cleared Under Organon Teknika Corporation

BK000042 BioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name:BacT/ALERT Culture Bottles
Cleared Date: 15-FEB-2002

BK020022 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT SN Culture Bottle
Cleared Date: 10-OCT-2002

BK020023 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT SA Culture Bottle
Cleared Date: 10-OCT-2002

BK020060 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:NuclieSens HIV-1 QT RNA External
Controls
Cleared Date: 18-DEC-2002

BK030034 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT BPN Culture Bottle
Cleared Date: 18-JUL-2003

BK030035 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT BPA Culture Bottle
Cleared Date: 06-AUG-2003

BK030075 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT BPN Culture Bottles
Cleared Date: 08-MAR-2004

BK030076 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT BPA Culture Bottles
Cleared Date: 08-MAR-2004

BK050037 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT BPA Culture Bottle

Cleared Date: 27-DEC-2005

- BK050043 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name:BacT/ALERT BPN Culture Bottle
Cleared Date: 27-DEC-2005
- BK090082 Biomat USA, Inc.
1311 Temple Avenue
City of Industry, CA 91746
Trade Name:SGP Version 7.0 (Plasma Management
System)
Cleared Date: 01-OCT-2010
- BK040036 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:GPS II Platelet Concentrate
Separation Kit
Cleared Date: 18-JUN-2004
Cleared Under Biomet, Inc.
- BK050016 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:Fibrostick Plasma Concentrator
Cleared Date: 20-JUL-2005
Cleared Under Biomet, Inc.
- BK070003 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:GPS II Platelet Concentration
Separation Kit with ACD-A
Plasmax Plasma Concentrator with
GPS Mini Platelet Concentrate
Separation Kit with ACD-A
Cleared Date: 22-FEB-2007
Cleared Under Biomet, Inc.
- BK070026 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:GPS III Mini Platelet Concentrate
Separation Kit with ACD-A
GPS III Platelet Concentrate
Separation Kit with ACD-A
GPS III Platelet Concentrate
Separation Kit with ACD-A Double
Kit
Cleared Date: 06-JUN-2007
Cleared Under Biomet, Inc.

BK070036 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:Vortech Concentration System
Cleared Date: 21-NOV-2007

BK080004 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:Clotalyst and GPS III Mini
Platelet Concentrate Separation
Kit with ACD-A
Clotalyst and GPS III Platelet
Concentrate Separation Kit with
ACD-A
Cleared Date: 19-DEC-2008

BK110040 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name:Clotalyst Kit with GPS(R)III
Separator
Cleared Date: 23-DEC-2011

BK970015 Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name:CEQer RBC Assay
Cleared Date: 18-SEP-1998

BK970016 Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name:CEQer PRP Assay
Cleared Date: 18-SEP-1998

BK970018 Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name:STELLeR CD34 Assay
Cleared Date: 18-AUG-1998

BK980035 Biopool International, Inc.
1230 Wilson Drive
West Chester, PA 19380-4254
Trade Name:SliDe Chek
Cleared Date: 11-JUN-1999

BK090037 Biosafe SA
Route du Petit-Eysins
Eysins, Vaud Switzerland 1262
Trade Name:CryoSC Freezing Bag
Cleared Date: 22-MAR-2010

BK110022 Biosafe SA
Route du Petit-Eysins
Eysins, Vaud Switzerland 1262
Trade Name:Sepax Cell Separation and single
use kits
Cleared Date: 28-OCT-2011

BK840028 Biotech Research Laboratories, Inc.
1600 East Gude Drive
Rockville, MD 20850
Trade Name:Run Control for HBsAg Assay
Cleared Date: 25-JAN-1985

BK090069 Biotechnology Institute, SL.
C/Leonardo Da Vinci 14B, 1B.
01510 Minano (Alava)
Alava, Spain 01510
Trade Name:Endoret Kit
Secondary Product Code: FMI, GKT
Cleared Date: 01-FEB-2010

BK060066 Biotest AG
Postfach 10 20 40
D-63266 Dreiech, Germany
Trade Name:TANGO Automated Blood Bank
Analyzer System, Version 3.0
Service Pack 4
Cleared Date: 17-JAN-2007

BK950015 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:Biotest DRB-SSO Typing Kit
Cleared Date: 09-JUN-1995

BK960061 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:Biotest DQB-ELPHA
Cleared Date: 04-AUG-1997

BK960086 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:Biotest High Resolution
Supplementary Kit
Cleared Date: 03-JUL-1997

BK980007 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:BIOTEST DRB-ELPHA Low Resolution
(Enzyme Linked Probe Hybridization
Assay)
Cleared Date: 26-JAN-1999

BK980033 Biotest Diagnostics Corporation

66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:LYMPHOSCREEN ABC 60
Cleared Date: 15-DEC-1999

BK980044 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:Lymphoscreen DR 30 x 2
Cleared Date: 15-DEC-1999

BK020004 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name:Biotest HLA SSP Kit
Cleared Date: 07-AUG-2002

BK080012 Biotest Medical Diagnostics GmbH
P.O. Box 10 21 50
63267 Dreiech, Germany
Trade Name:(1) Seraclone Control ABO+Rh
(2) Coombscell-E
(3) MLB2
Cleared Date: 23-JUL-2008

BK080013 Biotest Medical Diagnostics GmbH
P.O. Box 10 21 50
63267 Dreiech, Germany
Trade Name:Alsevers Solution (510(k) exempt
but part of system)
Solidscreen II Control B
Solidscreen Negative Control
Tango Optimo Automated Blood Bank
Analyzer System with version 3.1
Cleared Date: 23-JUL-2008

BK820009 Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, Germany
Trade Name:Anti-HLA Leukocyte Typing Serum
Cleared Date: 20-JAN-1983

BK820011 Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, Germany
Trade Name:Microdroplet Testing Tray
(Lymphotype ABC-72 Well)
Cleared Date: 20-JAN-1983

BK830027 Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, Germany
Trade Name:Microtest Testing Tray (HLA-DR
Wells)
Cleared Date: 26-APR-1984

BK890015 Blackhawk BioSystems, Inc.

12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Blood Screening/Diagnostic Serum
Controls
Cleared Date: 17-APR-1992

BK890019 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Blood Bank Saline
Cleared Date: 18-JUL-1990

BK920008 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:VIROTROL
Cleared Date: 17-SEP-1992

BK920028 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Virotrol HIV-2
Cleared Date: 03-JUN-1993

BK930016 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Virotrol I Reagents (CMV)
Cleared Date: 16-NOV-1993

BK930033 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Virotrol HIV-Ag
Cleared Date: 27-SEP-1995

BK930034 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Virotrol III
Cleared Date: 27-JUL-1994

BK950011 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:Viroclear
Cleared Date: 28-AUG-1995

BK960085 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:VIROTROL II
Cleared Date: 03-OCT-1997

BK000041 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583

Trade Name:Viroclear
Cleared Date: 28-DEC-2000

BK060052 Blackhawk BioSystems, Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name:AmpliTrol III
Cleared Date: 07-NOV-2006

BK960044 Blood Bank Computer Systems, Inc.
1501 West Valley Highway, North
Suite 101
Auburn, WA 98001
Trade Name:Blood Bank Control System
Cleared Date: 15-OCT-1997

BK040056 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name:Blood Bank Control System (BBCS) -
5.0
Cleared Date: 22-OCT-2004

BK040087 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name:BBCS Lab Interface Application
(BBCS Lab) - 5.0L
Cleared Date: 15-FEB-2005

BK050013 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name:BBCS Mobile Application - 5.0M
Cleared Date: 01-JUN-2005

BK090081 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name:BBCS Hospital Interface
Application (BBCSH), H 1.0.0
Cleared Date: 20-JAN-2010

BK120028 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name:BBCS BloodTrack Interface
Application (BBCSBT), BT1.0.0
Blood Bank Control System - V. 5.0
Cleared Date: 21-JUN-2012

BK940048 BloodCare
9000 Harry Hines Blvd.
Dallas, TX 75235
Trade Name:LifeTrak /Lab (a.k.a. Lab*Care) -
V. 2.01
Cleared Date: 01-OCT-1998

BK100051 Boekel Scientific, Inc
855 Pennsylvania Blvd.
Feasterville, PA 19053
Trade Name:Boekel Plasma Thawer, Model 301000
Cleared Date: 22-APR-2011

BK940025 Boston Scientific, Inc.
1 Boston Scientific Place
Natick, MA 01760-1537
Trade Name:Katzen Thrombolysis Guideware
Cleared Date: 24-JAN-1996

BK890009 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Meguon, WI 53092
Trade Name:Frozen Cell Panel Tray (Human)
Cleared Date: 02-AUG-1989

BK890010 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Meguon, WI 53092
Trade Name:Leukocyte Typing Serum Trays
(Human)
Cleared Date: 02-AUG-1989

BK890011 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Meguon, WI 53092
Trade Name:Leukocyte Typing Serum Trays
(Human)
Cleared Date: 02-AUG-1989

BK960049 CIS-US, Inc.
10 de Angelo Drive
Bedford, MA 01730
Trade Name:DoseWriter
Cleared Date: 25-MAR-1998

BK950024 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:COBE Platelet Filtration and
Storage Set
Cleared Date: 29-NOV-1995
Cleared Under COBE BCT

BK950056 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:Cobe Spectra LRD Leukoreduction
(System Versions)
Cleared Date: 31-JAN-1996
Cleared Under COBE BCT

BK950065 COBE Cardiovascular, Inc.
1201 Oak Street

Lakewood, CO 80215
Trade Name:Cobe Spectrum Apheresis System
(stem cell collection)
Cleared Date: 28-OCT-1998
Cleared Under COBE BCT

BK960076 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra LRS Turbo System
Cleared Date: 14-JUL-1997
Cleared Under COBE BCT

BK970005 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:Focussed System
Cleared Date: 13-OCT-1998
Cleared Under COBE BCT

BK970023 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:Collection of pRBC Using the
Focussed System
Cleared Date: 13-OCT-1998
Cleared Under COBE BCT

BK980004 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra Apheresis System
Anticoagulant Free Flow
Restriction
Cleared Date: 09-JUL-1998
Cleared Under COBE BCT

BK990025 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:Cobe Trima
Cleared Date: 07-APR-2000
Cleared Under COBE BCT

BK990040 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name:COBE Trima with the r/LS RBC
Leukoreduction Filter
Cleared Date: 03-MAR-2000
Cleared Under COBE BCT

BK050033 COBE Cardiovascular, Inc.
14401 West 65th Way
Arvada, CO 80004-3599
Trade Name:COBE Angel Whole Blood Separation
System

Cleared Date: 22-AUG-2005
Cleared Under COBE BCT

BK060010 COBE Cardiovascular, Inc.
14401 West 65th Way
Arvada, CO 80004-3599
Trade Name:COBE Angel Whole Blood Separation
System
Cleared Date: 27-FEB-2006

BK020020 CSL Behring AG
Wankdorfstrasse 10
3014 Bern, Switzerland
Trade Name:System for Plasma Identification
(SPI) - 1.0
Cleared Date: 30-OCT-2002
Cleared Under ZLB Behring AG

BK050078 CSL Behring AG
Wankdorfstrasse 10
3014 Bern, Switzerland
Trade Name:System for Plasma Identification
(SPI) - 2.0.0
Cleared Date: 22-DEC-2005

BK110023 CSL Behring AG
Wankdorfstrasse 10
3014 Bern, Switzerland
Trade Name:System for Plasma Identification
(SPI), version - 3.1.0
Cleared Date: 08-JUN-2011

BK090054 Calimex USA Corporation
258 Hollister Avenu
Alameda, CA 94501
Trade Name:Picture-ID
Cleared Date: 11-JAN-2010

BK110070 Calimex USA Corporation
258 Hollister Avenu
Alameda, CA 94501
Trade Name:eOrders, Version 1 - 1
Cleared Date: 17-FEB-2012

BK040002 Care Fusion, Inc.
1430 Spring Hill Road, Suite 510
McLean, VA 22102
Trade Name:wBlood Care - 1.0
Cleared Date: 10-NOV-2004

BK080035 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:COBE Spectra Apheresis System
Trima Accel Automated Blood
Component Collection System
Cleared Date: 29-AUG-2008

BK080043 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Atreus Whole Blood Processing
System
Cleared Date: 29-SEP-2008

BK080058 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Trima Accel Automated Blood
Component Collection System
Cleared Date: 25-NOV-2008

BK090003 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Trima Accel System
Cleared Date: 16-FEB-2010

BK100032 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Trima Accel System Version 6.0
Cleared Date: 06-AUG-2010

BK110009 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Trima Accel Automated Blood
Component Collection System
Cleared Date: 31-MAY-2011

BK110051 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Trima Accel Automated Blood
Component Collection System
version 5.1.8
Cleared Date: 20-DEC-2011

BK110068 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name:Trima Accel Automated Blood
COmponent Collection System
Cleared Date: 23-MAR-2012

BK990015 Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name:LifeTrak/Distribution - 2.03
Cleared Date: 22-OCT-1999

BK990027 Carter BloodCare
2205 Highway 121

Bedford, TX 76021
Trade Name:LifeTrak/Donor - 2.03
Cleared Date: 15-DEC-1999

- BK020051 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name:Cascade Medical Fibrinet,
Autologous Platelet System
Cleared Date: 20-DEC-2002
- BK060006 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name:Cascade Medical FIBRINET System
Cleared Date: 16-FEB-2006
- BK120008 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name:FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012
- BK120009 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name:FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012
- BK030033 Celera Diagnostics, LLC
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name:ViroSeq HIV-1 Genotyping System
Cleared Date: 11-JUN-2003
- BK030088 Celera Diagnostics, LLC
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name:ViroSeq HIV-1 Genotyping System
v2.0
Cleared Date: 22-JAN-2004
- BK060049 Celera Diagnostics, LLC
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name:ViroSeq HIV-1 Genotyping System
Cleared Date: 31-AUG-2006
- BK080026 Celera Diagnostics, LLC
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name:ViroSeq HIV-1 Genotyping System
v2.0
Cleared Date: 10-JUL-2008
- BK880002 Cellular Products
688 Main Street

Buffalo, NY 14202
Trade Name:Blood Bank Refrigerator
Cleared Date: 04-MAY-1988

BK950010 Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355
Trade Name:CAPTIA CMV-TA EIA
Cleared Date: 22-MAR-1995

BK950051 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:Pathnet Blood Center (L-2510)
Cleared Date: 16-JUL-1997

BK950053 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:Pathnet Blood Bank Transfusion (L-2300)
Cleared Date: 16-JUL-1997

BK950055 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:Pathnet Blood Bank Donor (L2400)
Cleared Date: 16-JUL-1997

BK960024 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:PathNet Worksystem Blood Bank
Transfusion (L2812)
Cleared Date: 16-JUL-1997

BK990007 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:HNA Millennium PathNet Blood Bank
Transfusion
Cleared Date: 02-NOV-1999

BK030028 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:Cerner Millennium PathNet Blood
Bank Donor (PA-22200) - 2003.01
Cleared Date: 19-AUG-2003

BK060037 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name:Cerner Bridge Medical Transfusion
Administration and Specimen
Collections - 3.3
Cleared Date: 24-MAY-2007

BK860025 Cetus Corporation
1400 53rd Street
Emeryville, CA 94608
Trade Name:Pro Group System
Cleared Date: 27-APR-1987

BK050021 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name:Charter Medical Transfer Set
Cleared Date: 22-JUL-2005

BK060042 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name:Cell Freeze Liquid Nitrogen
Freezing Container
Cleared Date: 03-OCT-2008

BK100049 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name:Cell-Freeze® Cryogenic Storage
Container
Cleared Date: 07-DEC-2010

BK910003 CharterMed, Inc.
3948-A West Point Blvd.
Winston-Salem, NC 27103
Trade Name:CharterMed Blood Freezing Bag
Cleared Date: 11-MAR-1993

BK960043 CharterMed, Inc.
3948-A West Point Blvd.
Winston-Salem, NC 27103
Trade Name:Charter Med Transfer Bags
Cleared Date: 11-SEP-1996

BK000049 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Chiron CPT Pooling Software,
Version 2.0.0.2
Cleared Date: 04-DEC-2001

BK010025 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Chiron Procleix NAT Tracker - 1.0E
Cleared Date: 03-JAN-2002
Cleared Under Rubin & Poor

BK030030 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Procleix NAT Tracker

Cleared Date: 23-MAY-2003
Cleared Under Rubin & Poor

- BK040058 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Chiron CPT Pooling Software,
Version 2.0.0.2
Cleared Date: 28-JUL-2004
- BK040072 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Procleix NAT Tracker Software
Version 2.1
Cleared Date: 04-NOV-2004
- BK050004 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Procleix Optiva RAS
Cleared Date: 08-APR-2005
- BK060005 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:Chiron Procleix NAT Tracker - 3.0
Cleared Date: 01-MAR-2006
- BK070007 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name:PROCLEIX NAT TRACKER
Cleared Date: 06-MAR-2007
- BK100014 Circle Biologic, LLC
3650 Annapolis Lane, Suite 105
Minneapolis, MN 55447
Trade Name:Autologous Fluid Concentrator
(AFC) System
Changed with 6/25/10 Submission
to: "Autologous Platelet
Concentrator (APC)(TM) System
Cleared Date: 09-JUL-2010
- BK840008 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:IBM 2991 - Change of Ownership
Cleared Date: 08-JUN-1984
- BK840009 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:IBM 2997 - Change of Ownership
Cleared Date: 08-JUN-1984

BK870022 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra Blood Component
Separator
Cleared Date: 20-JUN-1988

BK900002 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra: Simultaneous
Collection of Platelets and Plasma
Cleared Date: 21-JUN-1990

BK900003 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra: Change in
Anticoagulant Ratio
Cleared Date: 14-NOV-1990

BK900004 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra: Single Needle
System
Cleared Date: 21-JUN-1990

BK910020 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE SPECTRATHERM
Cleared Date: 02-NOV-1992

BK920011 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:Cobe Spectra with PCM
Cleared Date: 15-MAY-1995

BK920036 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra Single-Needle
Extended Life Platelet (ELP) Set
Cleared Date: 06-APR-1993

BK930017 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra Apheresis System
(Triple Platelet)
Cleared Date: 27-JUL-1994

BK940016 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215

Trade Name:COBE Spectra Version 4
Cleared Date: 20-SEP-1994

BK950030 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name:COBE Spectra Extended Life
Platelet Set
Cleared Date: 15-FEB-1996

BK970007 Community Bio-Resources, Inc.
2197 Parkway Lake Drive
Hoover, AL 35244
Trade Name:Donor Information System - 1.0
Cleared Date: 09-APR-1997

BK960060 Community Blood Center of Greater Kansas
City
4040 Main Street
Kansas City, MO 64111
Trade Name:CBC Blood System, Version 1.2
Cleared Date: 20-NOV-1997

BK110048 Community Blood Centers of South Florida
1700 North State Road 7
Lauderhill, FL 33313
Trade Name:Regulated Software Application
(RSA) - 1.0
Cleared Date: 12-JAN-2012

BK920006 Connaught Laboratories Limited
Discovery Drive
Swiftwater, PA 18370
Trade Name:CONTINENTAL REFRIG. BLD.BNK. MODEL
C-BBRA-1S
Cleared Date: 17-JUL-1992

BK970010 Controlled Chemicals, Inc.
317 S. Division
Suite 9
Ann Arbor, MI 48104
Trade Name:CryoGuard Thermal Exposure
Indicator
Cleared Date: 26-AUG-1997

BK940026 Cook, Inc.
925 S. Curry Pike
Bloomington, IN 47402
Trade Name:Roubin Infusion Catheter
Cleared Date: 29-JUN-1995

BK830008 Cooper Biomedical
1230 Wilson Drive
West Chester, PA 19380
Trade Name:W.A.R.M.
Cleared Date: 21-JUN-1983

BK850008 Cooper Biomedical
1 Technology Court
Malvern, PA 29355
Trade Name:H.P.C.
Cleared Date: 09-JAN-1986

BK850009 Cordis Laboratories, Inc.
2140 North Miami Avenue
Miami, FL 33127
Trade Name:CORDIA HTLV-I
Cleared Date: 03-OCT-1985

BK820007 Cry-O-Safe, Inc.
999 Airport Road
Lakewood, NJ 08701
Trade Name:Plasma Safe
Cleared Date: 26-JUL-1982

BK820018 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:Dideco BT Series
Cleared Date: 16-DEC-1982

BK820021 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:Dideco BT790/A
Dideco BT792
Cleared Date: 03-JAN-1983

BK830015 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:Dideco BT 125
Dideco BT 225
Dideco BT 375
Dideco BT 691
Cleared Date: 31-OCT-1983

BK830016 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:Dideco Progress BT 790/A
Cleared Date: 07-FEB-1984

BK840011 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:BT 765 Blood Cell Separator
Equipment
Cleared Date: 10-APR-1985

BK840012 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:BT 765 Elutriation Pump

Cleared Date: 06-FEB-1985

BK870003 Cryosan Inc.
850 Providence Highway
Dedham, MA 02026
Trade Name:Cryo-Pak™ System
Cleared Date: 17-APR-1987

BK820014 Cutter Biological
4th&Paker St,
Berkley, CA 94701
Trade Name:Plasma Pooling Bags
Cleared Date: 08-FEB-1983

BK840010 Cutter Biological
4th&Paker St,
Berkley, CA 94701
Trade Name:CLX Transfer Bag
Cleared Date: 15-AUG-1984

BK860001 Cutter Biological
4th&Paker St,
Berkley, CA 94701
Trade Name:Leukotrap System
Cleared Date: 05-AUG-1986

BK860040 Cutter Biological
4th&Paker St,
Berkley, CA 94701
Trade Name:Blood Collection Unit w/o
Anticoagulant
Cleared Date: 24-JUN-1987

BK960012 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name:Cyto Therm (T-S)
Cleared Date: 15-APR-1996
Cleared Under Photo-Therm

BK980042 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name:CytoTherm J
Cleared Date: 07-JAN-1999
Cleared Under Photo-Therm

BK060027 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name:CytoTherm Plasma Thawing System
Cleared Date: 01-AUG-2006

BK060063 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name:CytoTherm Cryoprecipitate Thawer,

Model CT-4T.6C
Cleared Date: 04-MAY-2007

BK080019 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name: CytoTherm Plasma Thawing System
Cleared Date: 16-JUL-2008

BK950060 Cytosol Laboratories, Inc.
55 Messina Drive
Braintree, MA 02184-6783
Trade Name: Y-Type Rejuvenation Set PN7212
Cleared Date: 25-NOV-1996

BK000022 DENCO, INC.
P.O. BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 18-APR-2000

BK990041 DENCO, INC.
P.O. BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 21-DEC-1999

BK950019 DUPACO
2620 TEMPLE HEIGHTS DR.
OCEANSIDE, CA 92056
Trade Name: DUPACO BLOOD/FLUID WARMING SET
D25416
Cleared Date: 27-APR-1995

BK950038 DUPACO
2620 TEMPLE HEIGHTS DR.
OCEANSIDE, CA 92056
Trade Name: Dupaco Counterflo 300 Blood/Fluid
Warmer
Cleared Date: 01-SEP-1995

BK020057 Data Innovations Inc.
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: imExpress - 7.2.5
Cleared Date: 29-JUL-2003
Cleared Under Data Innovations

BK060053 Data Innovations Inc.
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager - 8.05.01.10
Cleared Date: 05-JAN-2007

BK080052 Data Innovations Inc.
120 Kimball Ave., Suite 100
South Burlington, VT 05430

Trade Name:INSTRUMENT MANAGER - V 8.07
Cleared Date: 28-OCT-2008

BK100046 Data Innovations Inc.
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name:Instrument Manager - 8.10.01
Cleared Date: 12-AUG-2010

BK980031 Defense Blood Standard System
5205 Leesburg Pike
Suite 1000
Falls Church, VA 22041
Trade Name:DBSS - 3.00
Cleared Date: 31-AUG-1998
Cleared Under Department of Defense

BK070035 Defense Blood Standard System
5205 Leesburg Pike
Suite 1000
Falls Church, VA 22041
Trade Name:Defense Blood Standard System
(DBSS) - 10.0.0
Cleared Date: 22-MAY-2008

BK970021 Department of Veterans Affairs
P.O. Box 5000
VA Hines Medical Center
Hines, IL 60141
Trade Name:Vista Blood Bank Software (V5.2)
Cleared Date: 23-APR-1999

BK060043 Department of Veterans Affairs
P.O. Box 7008
Hines, IL 60141-7008
Trade Name:Vista Blood Establishment Computer
Software (VBECS) - 1.0
Cleared Date: 19-OCT-2006

BK830025 Dia Tech
2525 Shader Road
Orlando, FL 328
Trade Name:DiaCent 2 Automated Cell
Washer/Centrifuge
Cleared Date: 10-JAN-1984

BK840001 Dia Tech
2525 Shader Road
Orlando, FL 328
Trade Name:DIACENT 1, Automated Cell
Washer/Centrifuge
Cleared Date: 19-MAR-1984

BK870007 DiaClin Laboratories, Inc.
450 10th Circle North
Nashville, TN 37203
Trade Name:SEOPF ROP Tray

Cleared Date: 04-APR-1990

BK110036 Diaspect Medical GMBH
800 E. Leigh Street
Suite 206-5
Richmond, VA 23219
Trade Name:DiaSpect Hemoglobin T and DiaSpect
Hemoglobin Cuvettes
Cleared Date: 01-NOV-2011

BK970013 Digi-Trax Corporation
1550 Barclay Boulevard
Buffalo Grove, IL 60089
Trade Name:Donor-ID
Cleared Date: 27-FEB-1998

BK000020 Digi-Trax Corporation
1550 Barclay Boulevard
Buffalo Grove, IL 60089
Trade Name:Digi-Trax Donor-ID - 2.0
Cleared Date: 20-APR-2000

BK010049 Digi-Trax Corporation
1550 Barclay Boulevard
Buffalo Grove, IL 60089
Trade Name:Donor-ID - 2.2
Cleared Date: 26-APR-2002

BK850006 Division of Immunologic Oncology
3900 Reservoir Rd.,NW,Box 63,Med-Den
Bld
Washington, DC 20007
Trade Name:GTU DR/DQ Typing Tray
Cleared Date: 25-APR-1985

BK980009 Dominion Biologicals Limited
5 Isnor Drive
Dartmouth, Nova Scotia Canada B3B1M1
Trade Name:Coombs Control Cells (IgG Coated)
Cleared Date: 30-OCT-1998

BK070065 Duley Hopkins and Associates
1200 Mountain Creek Road
215
Chattanooga, TN 37405
Trade Name:Blood Bank Information Management
System (BBIMS) - V2.05.01
Cleared Date: 25-APR-2008

BK090079 Duley Hopkins and Associates
1200 Mountain Creek Road
215
Chattanooga, TN 37405
Trade Name:Blood Bank Information Management
System (BBIMS V2.05.01)
Cleared Date: 13-JAN-2010

BK030056 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, United
Kingdom
Trade Name:Dynal Reli SSO HLA-A Typing Kit
Cleared Date: 29-JAN-2004

BK030057 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, United
Kingdom
Trade Name:Dynal Reli SSO HLA-B Typing Kit
Cleared Date: 29-JAN-2004

BK030058 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, United
Kingdom
Trade Name:DYNAL RELI SSO HLA-Cw Typing Kit
Cleared Date: 29-JAN-2004

BK030059 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, United
Kingdom
Trade Name:Dynal RELI SSO HLA-DQB1 Typing Kit
Cleared Date: 29-JAN-2004

BK030060 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, United
Kingdom
Trade Name:DYNAL RELI SSO HLA-DRB Typing
System.
Cleared Date: 29-JAN-2004

BK050012 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, United
Kingdom
Trade Name:Dynal RELI SSO HLA-DRB1 Typing Kit
-
For Use as a manual asssay or with
the AutoRELI Instrument
Cleared Date: 18-MAY-2005

BK960041 Dynamic Healthcare Technologies, Inc.
101 Southhall Lane, Suite 210
Maitland, FL 32751
Trade Name:Transfusion Service Mgr.
Cleared Date: 16-DEC-1997

BK840004 Dynatech Laboratories, Inc.
900 Slaters Lane
Alexandria, VA 22314
Trade Name:MicroBBank 220 Automated
Microplate Reader
Cleared Date: 18-MAY-1984

BK850013 Dynatech Laboratories, Inc.
900 Slaters Lane
Alexandria, VA 22314
Trade Name:MicroBank System
Cleared Date: 08-OCT-1985

BK840003 E.I. duPont de Nemours & Company
Medical Products Department
Wilmington, DE 19898
Trade Name:DuPont SCD
Cleared Date: 07-NOV-1984

BK910022 E.I. duPont de Nemours & Company
Medical Products Department
Wilmington, DE 19898
Trade Name:Du Pont Sorvall RC 3B Plus
Du Pont Sorvall RC 3C Plus
Centrifuge
Cleared Date: 21-JAN-1992

BK840018 EK Industries, Inc.
411 Kay Avenue
Addison, IL 60101
Trade Name:Copper Sulfate Solution (for
women)
Cleared Date: 11-DEC-1984

BK840019 EK Industries, Inc.
411 Kay Avenue
Addison, IL 60101
Trade Name:Copper Sulfate Solution (for men)
Cleared Date: 11-DEC-1984

BK090044 Eclypsis Corporation
450 Lapp Road
Malvern, PA 19355
Trade Name:Sunrise Blood Bank version 2.0 SP2
Cleared Date: 13-NOV-2009

BK900006 Electrolux SARL
1317 F St. NW, suite 150
Washington, DC 20004
Trade Name:Blood Chain Thermostabilizer
RCB42P
Cleared Date: 18-JUL-1990

BK860018 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)

Tucson, AZ 85716
Trade Name:SEBRA Model 1150 (Blood Weighth
Monitor)
Cleared Date: 11-JUL-1986

BK860019 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)
Tucson, AZ 85716
Trade Name:SEBRA Model 1300 (Tube Stripper)
Cleared Date: 29-SEP-1986

BK870023 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)
Tucson, AZ 85716
Trade Name:Sebra Model #1500 Centrifuge Cup
Blood Bag Holder
Cleared Date: 25-SEP-1986

BK900025 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)
Tucson, AZ 85716
Trade Name:SEBRA Model #2470, Mobile Tube
Sealer
Cleared Date: 26-JUN-1991

BK900026 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)
Tucson, AZ 85716
Trade Name:SEBRA MODEL #1040, DIGITAL BLOOD
SHAKER/WEIGHT MONITOR
Cleared Date: 26-JUN-1991

BK900029 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)
Tucson, AZ 85716
Trade Name:Sebra Model #2390, Mobile Tube
Sealer
Cleared Date: 26-JUN-1991

BK910015 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA
Plaza)
Tucson, AZ 85716
Trade Name:Sebra Model #1290, Blood/Platelet
Coolant
Cleared Date: 11-SEP-1991

BK110035 Estar Technologies LTD
420 Lexington Avenue
Suite 2400
New York, NY 10170
Trade Name:TropoCells Autologous Platelet

Preparation Kit
Cleared Date: 28-MAR-2012

BK920002 Ethox Corp.
251 Seneca St,
Buffalo, NY 14204
Trade Name:Ethox Transfer Pack
Cleared Date: 17-SEP-1992

BK830010 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Transfer Pack Unit(s) with
Sterile Connector
Cleared Date: 23-AUG-1988
Cleared Under Travenol Laboratories

BK830011 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Closed Apheresis Kit for Extended
Platelet Storage
Cleared Date: 27-MAY-1983
Cleared Under Travenol Laboratories

BK830009 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Plasma-Gard
Cleared Date: 25-JAN-1984
Cleared Under Travenol Laboratories

BK860015 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Apheresis Kit/Extended Plate.
Stor. & Plas. Coll.
Cleared Date: 03-JUL-1986
Cleared Under Travenol Laboratories

BK860029 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Isoradial Separation Chamber
Cleared Date: 28-NOV-1986
Cleared Under Travenol Laboratories

BK860035 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:CS-3000 Bld Cell Separator Bld
Sample Containers
Cleared Date: 26-FEB-1987
Cleared Under Travenol Laboratories

BK870017 Fenwal Inc
Three Corporate Drive

Lake Zurich, IL 60047
Trade Name:Fenwal LS-300 Centrifuge
Cleared Date: 16-NOV-1987
Cleared Under Fenwal Laboratories

BK880023 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Fenual CS3000 Blood Cell Separator
Cleared Date: 13-JUN-1989
Cleared Under Travenol Laboratories

BK900005 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Closed System Apheresis Kit-
CS3000 Blood Cell Separator
Cleared Date: 05-JUN-1990
Cleared Under Baxter Healthcare
Corporation

BK900016 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Closed System Apheresis Kit CS-
3000 Blood Cell Separator (single
venous access for platelet
collection)
Cleared Date: 07-JUN-1991
Cleared Under Baxter Healthcare
Corporation

BK900020 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Optum Platelet Separation Chamber
Cleared Date: 07-NOV-1990
Cleared Under Baxter Healthcare
Corporation

BK910014 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Sepacell R-200; Pre-Storage
Leukocyte Depletion Set for Red
Blood
Cleared Date: 18-SEP-1991
Cleared Under Baxter Healthcare
Corporation

BK910032 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:OptiPress
Cleared Date: 03-JUN-1993
Cleared Under Baxter Healthcare
Corporation

BK920003 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Fenwal Needle/Tube Sampling
Protector/Safety Cover
Cleared Date: 12-MAR-1992
Cleared Under Baxter Healthcare
Corporation

BK920029 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:30-mL Collection Chamber for CS-
3000 Plus Blood Cell Separator
Cleared Date: 06-MAY-1994
Cleared Under Baxter Healthcare
Corporation

BK920032 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Sepacell Pre-storage Leukocyte
Depletion Set for Red Cell
Cleared Date: 07-JUN-1993
Cleared Under Baxter Healthcare
Corporation

BK920038 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Closed System Apheresis Kit with
Integral Leukocyte Removal Filter
Cleared Date: 27-JUL-1994
Cleared Under Baxter Healthcare
Corporation

BK930029 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:AccesTM Management System (AMS)
Cleared Date: 20-JUN-1994
Cleared Under Baxter Healthcare
Corporation

BK940005 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Fenwal Bone Marrow Collection Kit
w/ Flexible Pre-filter and Inline
Filters and Fenwal Bone Marrow
Collection Stand
Cleared Date: 18-MAY-1994
Cleared Under Baxter Healthcare
Corporation

BK940009 Fenwal Inc

Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Optipress TM Automated Blood
Component
Cleared Date: 18-MAY-1994
Cleared Under Baxter Healthcare
Corporation

BK940013 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Ex Storage PL 732 Containers w/
Sepacell Filter for Leukocytes
Reduced Platelets
Cleared Date: 27-JUL-1994
Cleared Under Baxter Healthcare
Corporation

BK940023 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Accessory Weight Scale for Medical
Purposes
Cleared Date: 05-JUL-1994
Cleared Under Baxter Healthcare
Corporation

BK940036 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Storage Containers for CS-3000
Apheresis Kit
Cleared Date: 27-DEC-1994
Cleared Under Baxter Healthcare
Corporation

BK940040 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Sepacell PLS-10A,5A Leukocyte
Reduction Filter Platelet Products
Cleared Date: 28-FEB-1995
Cleared Under Baxter Healthcare
Corporation

BK940041 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Sepacell R-2000 Prestorage
Leukocyte Reduction Set for Red
Blood Cells
Cleared Date: 14-FEB-1995
Cleared Under Baxter Healthcare
Corporation

BK950013 Fenwal Inc
Three Corporate Drive

Lake Zurich, IL 60047
Trade Name:CS-3000 Plus (mononeuclear cells)
Cleared Date: 28-OCT-1998
Cleared Under Baxter Healthcare
Corporation

BK950016 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Pall BPF4 Leukocyte Reduction Set
for RBC
Cleared Date: 20-SEP-1995
Cleared Under Baxter Healthcare
Corporation

BK950023 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:CS-3000 Blood Cell Separator
Apheresis Kit
Cleared Date: 29-JUN-1995
Cleared Under Baxter Healthcare
Corporation

BK960005 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Amicus Separator
Cleared Date: 19-DEC-1996
Cleared Under Baxter Healthcare
Corporation

BK960083 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Hematype Segment Device
Cleared Date: 28-FEB-1997
Cleared Under Medical Safety Products,
Inc.

BK980041 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Sepacell Pre-Storage Leukocyte
Reduction Set for Red Cells
Cleared Date: 16-JUL-1999
Cleared Under Baxter Healthcare
Corporation

BK990009 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Fenwal Amicus Separator Collection
of Three Platelet Products
Cleared Date: 03-MAR-2000
Cleared Under Baxter Healthcare
Corporation

BK000039 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Amicus Separator, Concurrent
Collection of Red Blood Cells
Cleared Date: 26-AUG-2002
Cleared Under Baxter Healthcare
Corporation

BK000047 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Amicus Separator, Mononuclear Cell
Collection
Cleared Date: 31-JUL-2002
Cleared Under Baxter Healthcare
Corporation

BK010016 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Apheresis Data Integration System
(ADIS)
Cleared Date: 04-DEC-2001
Cleared Under Baxter Healthcare
Corporation

BK010033 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Cygnnet System
Cleared Date: 27-AUG-2002
Cleared Under Baxter Healthcare
Corporation

BK020008 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:LeukoConnect - Pre-Storage Sterile
Connect Leukoreduction Set with
SepacellFilter for Red Blood
Cells
Cleared Date: 10-DEC-2002
Cleared Under Baxter Healthcare
Corporation - I.V. Systems Division

BK020056 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:ALYX System
Cleared Date: 20-DEC-2002
Cleared Under Baxter Healthcare
Corporation

BK030085 Fenwal Inc
Three Corporate Drive

Lake Zurich, IL 60047
Trade Name:ALYX Component Collection System
and Amicus Separator System
Cleared Date: 15-MAR-2004
Cleared Under Baxter Healthcare
Corporation

BK040059 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Amicus Separator System
Cleared Date: 24-SEP-2004
Cleared Under Baxter Healthcare
Corporation - Transfusion Therapies
Division

BK040084 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:ALYX Component Collection System
Cleared Date: 15-MAR-2005
Cleared Under Baxter Healthcare
Corporation

BK050020 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:LeukoConnect - Pre-Storage Sterile
Connect Leukoreduction Set with
Sepacell Filter for Red Blood
Cells in additive solution
Cleared Date: 17-MAY-2005
Cleared Under Baxter Healthcare
Corporation

BK050038 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:AMICUS Separator System
Cleared Date: 03-NOV-2005
Cleared Under Baxter Healthcare
Corporation

BK060061 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:ALYX Component Collection System:
ALYX 2RBC-NLR Kit
Cleared Date: 09-FEB-2007
Cleared Under Baxter Healthcare
Corporation

BK080024 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:ALYX Component Collection System

Cleared Date: 24-JUN-2008

- BK080048 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:AMICUS Separator
Cleared Date: 02-OCT-2008
- BK080053 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:ALYX Component Collection System
Cleared Date: 22-DEC-2008
- BK090031 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:Bone Marrow Collection Kit and
Accessories
Cleared Date: 23-JUL-2009
- BK090058 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:AMICUS Separator System
Cleared Date: 18-FEB-2010
- BK090065 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:AMICUS Separator System
Cleared Date: 04-MAR-2010
- BK100041 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:Autopheresis - C Plasmapheresis
System
Cleared Date: 05-AUG-2010
- BK100050 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:Autopheresis-C Plasmapheresis
system
Cleared Date: 16-NOV-2010
- BK100056 Fenwal Inc
Three Corporate Drive
2nd Floor

Lake Zurich, IL 60047
Trade Name:ALYX Component Collection System
Cleared Date: 07-DEC-2010

BK110025 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:Software, Blood Ban, Stand Alone
Cleared Date: 22-AUG-2011

BK110030 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name:AMICUS Separator System with
Software Version 4.3
Cleared Date: 23-DEC-2011

BK110066 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Product Sample Pack
Cleared Date: 27-FEB-2012

BK110072 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Aurora Plasmapheresis System
Plasmacell-C Disposable Set
Cleared Date: 29-MAR-2012

BK920026 Fenwal, Inc.
25212 W. Illinois Route 120, RLP-34
Round Lake, IL 60073
Round Lake, IL 60073
Trade Name:SDP Microplate Assay Management
Software
Cleared Date: 30-JUL-1993
Cleared Under Genetic Systems Corporation

BK080018 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:Amicus Separator System
Cleared Date: 26-AUG-2008
Cleared Under Fenwal Blood Technologies

BK080033 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:PLASMALINK
Cleared Date: 22-AUG-2008
Cleared Under Fenwal Blood Technologies

BK100044 Fenwal, Inc.
Three Corporate Drive

Lake Zurich, IL 60047
Trade Name:Amicus Separator System
Cleared Date: 30-JUL-2010
Cleared Under Fenwal Blood Technologies

BK120018 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name:AMICUS Apheresis Kits
AMICUS Separator System
Cleared Date: 20-JUL-2012

BK110012 fresenius Kabi, LLC.
1501E. Woodfield Road
Schaumburg, IL 60173
Trade Name:CompoMat G5 and CompoMaster Net G5
System
Cleared Date: 02-AUG-2012

BK030022 Fresenius Medical Care North America
6675 185th Avenue NE
Suite 100
Redmond, WA 98052
Trade Name:Fresenius Compomat G4 &
Compomaster NT
Cleared Date: 11-JUL-2003
Cleared Under Fresenius Hemocare Inc.

BK040005 Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420-9192
Trade Name:Fresenius Compoguard &
Donationmaster NT
Cleared Date: 26-MAR-2004
Cleared Under Fresenius Hemocare Inc.

BK040076 Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420-9192
Trade Name:Compodock
Cleared Date: 17-DEC-2004
Cleared Under Fresenius Hemocare Inc.

BK880007 Fresenius USA/Seratronics Inc.
2637 Shadelands Drive
Walnut Creek, CA 94598
Trade Name:Fresenius AS104 Cell Separator
Cleared Date: 22-JUL-1996

BK880018 Fresenius USA/Seratronics Inc.
4090 Pike Lane
Concord, CA 94502
Trade Name:Astotherm IFT 200; IFT 220
Cleared Date: 25-AUG-1988

BK960066 Frigidaire Commercial Products Company
707 Robins St

Conway, AR 72032
Trade Name:Eagle Series Blood Storage
Refrigerator # ST30RGBB and ST50
Cleared Date: 30-AUG-1996

- BK960092 Fujirebio America Inc.
30 Two Bridges Road
Suite 250
Fairfield, NJ 07004
Trade Name:Olympus PK CMV-PA System &
Controls
Cleared Date: 28-OCT-1998
- BK960070 Fujirebio Diagnostics, Inc
201 Great Valley Parkway
Malvern, PA 19355
Trade Name:Olympus PK-TP System Control Set
Cleared Date: 19-JUN-1997
Cleared Under SCIMEDX Corporation
- BK030007 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name:Olympus PK TP System
Cleared Date: 21-FEB-2003
- BK060062 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name:Olympus PK® TP Reagent System
Cleared Date: 25-JUN-2007
- BK070030 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name:Olympus PK CMV-PA Test System and
Controls
Olympus PK7300 Automated Blood
Bank Analyzer
Cleared Date: 20-SEP-2007
- BK940047 Fujirebio, Inc.
1129 Bloomfield Ave,
West Caldwell, NJ 07006
Trade Name:Olympus PK TP System Reactive
Control
Cleared Date: 29-NOV-1995
- BK920005 Futuremed
2076 Deer Park Avenue
Deer Park, NY 11729
Trade Name:AM-4
Cleared Date: 29-SEP-1994
- BK940055 Futuremed
2076 Deer Park Avenue
Deer Park, NY 11729

Trade Name:L Fusion Bags for Warming
Blood/Plasma w/ ANIMEC4
Cleared Date: 27-DEC-1994

BK050018 GE Medical Information Technologies
540 Northwest Highway
Barrington, IL 60010
Trade Name:Centricity Ultra Laboratory
Transfusion Medicine (Ultra TM) -
4.0
Cleared Date: 13-JUN-2005

BK010006 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Trima Automated Blood Component
Collection System
Cleared Date: 27-FEB-2002

BK010037 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Platelet collection sets for the
COBE Spectra Apheresis System and
the Trima Automated Blood
Component Collection System.
Cleared Date: 09-DEC-2002

BK010046 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Trima Automated Blood Collection
System (Single Stage)
Cleared Date: 18-SEP-2002

BK010050 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Trima Automated Blood Collection
System
Cleared Date: 18-SEP-2002

BK020015 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Vista Information System,
Independent Solution
Cleared Date: 15-JUL-2002

BK020041 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:COBE Spectra Apheresis
System/Blood component disposable
collection sets for apheresis
Cleared Date: 23-APR-2003

BK030021 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Vista Information System - 2.1
Cleared Date: 01-MAY-2003

BK030083 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Trima Accel
Cleared Date: 14-JAN-2004

BK040069 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Trima Automated Blood Component
Collection System - Blood
Component Sampling Accessory
Cleared Date: 28-OCT-2004

BK040086 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:COBE Spectra Apheresis System &
Trima Automated Blood Component
Collection System
Cleared Date: 15-MAR-2005

BK070001 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Vista Information System - 3.0
Cleared Date: 27-JUN-2007

BK070066 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Vista Information System, Version
3.0 with Medical Review Module
Cleared Date: 13-DEC-2007

BK080010 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:The Atreus Whole Blood Processing
System
Cleared Date: 27-JUN-2008

BK080029 Gambro BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name:Trima Accel Automated Blood
Component Collection System
Cleared Date: 18-MAY-2010

BK870024 Gambro Inc.
23872 Kelsey Road

Barrington, IL 60010
Trade Name:Gambro Welding Device WD2
Cleared Date: 02-NOV-1987

- BK820017 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Omni-Series Control
Cleared Date: 21-JAN-1983
- BK830012 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Omni Coombs Control Cells
Cleared Date: 13-JUN-1983
- BK830014 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Elu-Kit II
Cleared Date: 25-NOV-1983
- BK830019 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Microtear System
Cleared Date: 21-SEP-1983
- BK830026 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Micro-U Plate
Cleared Date: 08-DEC-1983
- BK850001 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma STS-M
Cleared Date: 05-APR-1985
- BK850002 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma STS Red Cell Diluent
Cleared Date: 05-APR-1985
- BK850005 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma STS-A
Cleared Date: 03-OCT-1986
- BK850019 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Micro-U Accessory Equipment
(Timer Device)

Cleared Date: 20-MAR-1986

BK850020 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Micro-U Accessory Equipment
Cleared Date: 20-MAR-1986

BK850021 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Micro-U Accessory Equipment
Cleared Date: 20-MAR-1986

BK850024 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Micro-U Coombs Wash Solution
Cleared Date: 20-MAR-1986

BK850025 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Micro-U Enhancement Reagent
Cleared Date: 20-MAR-1986

BK860024 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma N-HANCE
Cleared Date: 26-AUG-1986

BK880016 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:GammaZyme-B
Cleared Date: 25-AUG-1988

BK900021 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma-clone Control
Cleared Date: 26-OCT-1990

BK910001 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Peg
Cleared Date: 24-MAR-1992

BK930026 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma RQC-Kit
Cleared Date: 16-NOV-1993

BK960055 Gamma Biologicals, Inc.

3700 Mangum Road
Houston, TX 77092
Trade Name:Coombs Control Cells (EIgG) Strong
Cleared Date: 23-OCT-1996

BK960056 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Coombs Control Cells (EIgG) Weak
Cleared Date: 23-OCT-1996

BK960077 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma Re-ACT Centrifuge
Cleared Date: 18-SEP-1997

BK960078 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma ReACT Incubator
Cleared Date: 18-SEP-1997

BK960079 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma ReACT Antibody Detection
Strips
Cleared Date: 18-SEP-1997

BK960080 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma ReACT Diluent
Cleared Date: 18-SEP-1997

BK960081 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma ReACT Control Cells (EIgG)
Cleared Date: 18-SEP-1997

BK960090 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma EGA Kit
Cleared Date: 21-JUL-1997

BK970002 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Gamma-ReACT workstation
Cleared Date: 30-MAY-1997

BK970003 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092

Trade Name:Gamma-ReACT Reader
Cleared Date: 30-MAY-1997

BK970047 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name:Olympus System Control Reagent
Cleared Date: 11-DEC-1998

BK060050 Gaymar Industries, Inc.
1700 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706
Trade Name:Medi-Temp III, Model FW600
Blood/Fluid Warmer
Cleared Date: 07-NOV-2006

BK950002 Gen Trak, Inc.
5100 Campus Dr.
Plymouth Meeting, NJ 19462
Trade Name:CQententials DR DNA Typing Kit
Cleared Date: 15-MAY-1995

BK000051 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:The Chiron Procleix System
Cleared Date: 08-FEB-2002

BK010003 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:ChironProcleix HIV-1/HCV Controls
Cleared Date: 22-FEB-2002

BK010005 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:Chiron Procleix HIV/HCV
Proficiency Panel
Cleared Date: 01-OCT-2001

BK020045 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:Chiron Procleix System
Cleared Date: 21-NOV-2002

BK050007 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:Procleix System
Cleared Date: 29-APR-2005

BK050042 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:Procleix System for the Procleix

WNV Assay

Cleared Date: 15-NOV-2005

- BK060012 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:Procleix System
Cleared Date: 15-MAR-2006
- BK060021 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name:Procleix® TIGRIS® System for use
with the Procleix® WNV Assay
Cleared Date: 20-FEB-2007
- BK110002 Gen-Probe
550 West Avenue
Stanford, CT 06902
Trade Name:LIFECODES HLA-A eRES Typing Kit
for use with Luminex
LIFECODES HLA-B eRES Typing Kit
for use with Luminex
LIFECODES HLA-DRB 3, 4, 5 Typing
Kit for use with Luminex
LIFECODES HLA-DRB1 eRES Typing Kit
for use with Luminex
Cleared Date: 02-DEC-2011
- BK040019 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:Antibody Monitoring System Class I
and Class II (AMS1 and AMS1+2)
Cleared Date: 06-JUL-2004
Cleared Under GTI, INC
- BK040034 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:Lifecodes LifeScreen: A Luminex
100 Screening Assay for the
Detection of IgG Antibodies to HLA
Class I and Class II Molecules of
Human Origin
Cleared Date: 16-JUL-2004
Cleared Under GTI, INC
- BK040035 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:Lifecodes ID Class I: A Luminex
100 screening assay for the
qualitative detection of IgG panel
reactive antibodies (PRA) to HLA
Class I molecules
Lifecodes ID Class II: A Luminex

100 screening assay for the
qualitative detection of IgG panel
reactive antibodies (PRA) to HLA
Class II molecules

Cleared Date: 16-JUL-2004
Cleared Under GTI, INC

- BK050040 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:ThromboType (HPA 1-6, 15) and
ThromboType 1 (HPA 1)
Cleared Date: 20-JAN-2006
Cleared Under GTI, INC
- BK050054 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:GranType(TM)
Cleared Date: 02-MAR-2006
Cleared Under GTI, INC
- BK060038 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:MICROAMS
Cleared Date: 28-JUL-2006
Cleared Under GTI, INC
- BK070034 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:HLA EZ Type
Cleared Date: 10-JUL-2008
Cleared Under GTI, INC
- BK070045 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:Donor Screen HLA Class I and Class
II
Cleared Date: 30-JUL-2008
Cleared Under GTI, INC
- BK110011 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name:Lifecodes Class II ID v2
Cleared Date: 04-JUN-2012
- BK850003 Genesis BPS, LLC
65 Commerce Way
Hackensack, NJ 07601
Trade Name:Cryosan Pediatric Pack
Cleared Date: 05-APR-1985
Cleared Under Cryosan Inc.

BK950018 Genesis BPS, LLC
65 Commerce Way
Hackensack, NJ 07601
Trade Name:TOTAL CONTAINMENT DEVICE (TCD)
Cleared Date: 14-NOV-1995
Cleared Under DENCO, INC.

BK880025 Genetic Design Inc.
7019 Albert Pick Rd.; Suite H
Greensboro, NC 27409
Trade Name:HLA-DR Typing Trays
Cleared Date: 30-DEC-1988

BK870006 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name:HLA-B27 Antigen Typing Kit
Cleared Date: 20-JUL-1987

BK900011 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name:Genetic Systems Blood Virus
Software
Cleared Date: 15-MAR-1991

BK930031 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name:Espresso Cartridge Software for
Blood Virus Applications
Cleared Date: 24-FEB-1994

BK860022 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name:GTI-60 HLA Typing Trays
GTI-72 HLA Typing Trays
GTI-96 HLA Typing Trays
Cleared Date: 24-FEB-1987

BK910013 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name:GTI Pep Antibody Enhancement
Solution
Cleared Date: 23-JUN-1992

BK930014 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name:GTI Reduced Wash Elution Kit
Cleared Date: 28-OCT-1993

BK930032 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233

Trade Name:GTI ACE Antigen Capture ELISA for
Detection of IgG Antibodies to
Platelet Specific Antibodies
Cleared Date: 20-JUN-1994

BK950004 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name:GTI-PAK 2 Platelet Antibody
Screening Kit
Cleared Date: 15-MAY-1995

BK950005 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name:GTI-HLA 1, Class I Antibody
Screening Kit
Cleared Date: 19-MAY-1995

BK980005 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name:GTI PAT HPA-1 (PI) Genotyping Kit
Cleared Date: 23-APR-1999

BK000015 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name:Quick ID Solid Phase ELISA for
detection of Panel Reactive HLA
Class I IgG Antibodies (PRA)
Cleared Date: 17-OCT-2000

BK000031 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name:GTI-MACE (Modified Capture Elisa)
Cleared Date: 29-JAN-2001

BK990043 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name:B-Screen Solid Phase ELISA Assay
for Detection of IgG Antibodies to
HLA Class II Antigens
Cleared Date: 02-OCT-2000

BK010010 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name:Quik-ID Class II
Cleared Date: 01-OCT-2001

BK960059 Genetic Testing Institute, Inc. (GTI)
20925 Crossroads Circle
Suite 200
Waukesha, WI 53186

Trade Name:PAKAUTO Platelet Antibody
Screening Kit
Cleared Date: 22-OCT-1998
Cleared Under Genetic Testing Institute

- BK090002 Genetic Testing Institute, Inc. (GTI)
20925 Crossroads Circle
Suite 200
Waukesha, WI 53186
Trade Name:Lifecodes LifeScreen Deluxe
Cleared Date: 17-APR-2009
- BK050026 Greiner Bio One North America, Inc.
4238 Capital Drive
Monroe, NC 28110
Trade Name:Greiner Vacuette No Additive Tubes
Cleared Date: 07-JUL-2005
- BK050028 Greiner Bio One North America, Inc.
4238 Capital Drive
Monroe, NC 28110
Trade Name:Greiner Vacuette Clot Activator
Tube
Cleared Date: 07-JUL-2005
- BK030001 Greiner Bio-One GmbH
4238 Capital Drive
Monroe, NC 28112
Trade Name:Greiner Vacuette EDTA K3 Tube
Cleared Date: 26-FEB-2003
- BK030032 Greiner Bio-One GmbH
4238 Capital Drive
Monroe, NC 28112
Trade Name:Vacuette EDTA K2 Tube
Cleared Date: 18-JUL-2003
- BK840002 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Alpha Plasma Pooling Bottle II
Cleared Date: 13-JUL-1984
- BK840007 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Alpha Plasma Pooling Bottle
Cleared Date: 21-SEP-1984
- BK840014 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics V50 Surge Procedure
Cleared Date: 06-JUL-1984
- BK840021 Haemonetics Corporation
400 Wood Road

Braintree, MA 02184-9114
Trade Name:Haemonetics PCS Plasma Collection
System
Cleared Date: 03-JAN-1985

BK840022 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics 115 Cell Washer
Cleared Date: 24-OCT-1984

BK840025 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics 16 Programmed Pump
Cleared Date: 14-NOV-1984

BK860013 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:603-EX Extended Storage
Plateletpheresis Set
Cleared Date: 06-NOV-1987

BK870026 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics Ultralite Plasma
Collection System
Cleared Date: 17-MAR-1988

BK890007 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics 705 Time Saver
Platelet Pack
Cleared Date: 13-AUG-1990

BK900019 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Alpha Plasma Pooling Bottle II
(Significant Rev.)
Cleared Date: 14-AUG-1990

BK900022 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Plasma Pooling Bottle II
(Significant Revision)
Cleared Date: 11-OCT-1990

BK900027 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:790 ESP Collection Set
Cleared Date: 19-APR-1991

BK910009 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Alpha Plasma Pooling Bottle II
(Significant Rev.)
Cleared Date: 08-SEP-1991

BK920012 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:705FTSPP/790F
Cleared Date: 16-SEP-1992

BK920039 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Plasma Collection System PCS2
Cleared Date: 02-SEP-1993

BK930007 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:790 Extended Storage Platelet
Collection Set
Cleared Date: 16-NOV-1993

BK930008 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:791 A Fresh Frozen Plasma
Collection Set (Latham Bowl)
Cleared Date: 16-NOV-1993

BK930009 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:791 Fresh Frozen Plasma Collection
Set (Blow Molded Bowl)
Cleared Date: 16-NOV-1993

BK930013 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS Plus & Disp.Sets, List No.
890,790,791A,791
Cleared Date: 12-JAN-1994

BK940064 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Red Cell and Plasma Apheresis
Set/FOR USE WITH MCP PLUS
Cleared Date: 23-OCT-1995

BK950001 Haemonetics Corporation
400 Wood Road

Braintree, MA 02184-9114
Trade Name:Haemonetics RBC Apheresis Set for
MCS+(NO.831)
Cleared Date: 22-APR-1996

BK950006 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:List #890F Extended Storage Plt
Collection Set
Cleared Date: 09-JUN-1995

BK950007 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:ESP White Cell Filter (No. 790F)
Cleared Date: 28-JUN-1995

BK950033 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics PCS2
Cleared Date: 16-APR-1996

BK950034 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Double Product Collection (SDP-3)
Cleared Date: 15-FEB-1996

BK950063 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Red Blood Cell and Plasma
Collection Set for the MCS Plus
#823
Cleared Date: 22-JUL-1996

BK960006 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Double Unit Red Blood Cell
Apheresis Set MCS #833
Cleared Date: 15-OCT-1996

BK960022 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS+Double Unit RBC Apheresis Set-
Dry(LN832)
Cleared Date: 16-APR-1997

BK960023 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS+Red Cell & Plasma Apheresis
Set - Dry(LN822)

Cleared Date: 16-APR-1997

BK960095 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS+Apheresis System (LN8150)
Cleared Date: 11-APR-1997

BK970029 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Alpha Plasma Pooling Bottle II
(60-2227S)
Cleared Date: 07-JAN-1998
Cleared Under Alpha Therapeutic
Corporation

BK970034 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:LN994CF
Cleared Date: 15-SEP-1998

BK970041 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics Corp. Extended Storage
Platelet & Plasma Apheresis Set
with Saline Compensation & Pall
LRF-XL (LN994C)
Cleared Date: 16-NOV-1998

BK980040 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Citroflex Plalsticized PVC
Extended Storage Platelet Bag
Cleared Date: 07-JAN-1999

BK000002 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Model 215 Automated
Glycerolization and
Deglycerolization System
Cleared Date: 04-MAY-2001

BK990033 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS+ LN8150
Cleared Date: 20-JAN-2000

BK990044 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics LN832F

Two Unit Red Cells Disposable Set
with Leukocyte reduction Filter
Cleared Date: 27-OCT-2000

BK000048 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics LN832F
Cleared Date: 09-APR-2001

BK010035 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS+ Mobile Collection System
Cleared Date: 20-DEC-2002

BK020001 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Plasma Pooling Bottle II
Cleared Date: 29-MAR-2002

BK030031 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics Model 215 Automated
Glycerolyzation /
Deglycerolyzationand Cell Washing
System
Cleared Date: 10-SEP-2003

BK030062 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics Model 215 Automated
Glycerolization/deglycerolization
System
Cleared Date: 10-DEC-2003

BK030084 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics LN994CF-CPP-BA
Extended Storage Platelet and
Plasma Apheresis Set
Cleared Date: 09-JAN-2004

BK040001 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics 4mL Sampling System
Cleared Date: 27-FEB-2004

BK040020 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics LN994CF-BA Extended

Storage Platelet and Plasma
Apheresis Set with Leukocyte
Reduction Filter, and 4 mL
Sampling System.

Cleared Date: 29-MAR-2004

- BK040025 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:PCS2 Plasma Collection System
Cleared Date: 02-JUN-2004
- BK040041 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics MCS+8150 Apheresis
System
Cleared Date: 12-JUL-2004
- BK040077 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics Model 215 Automated
Glycerolization/Deglycerolization
System
Cleared Date: 21-DEC-2004
- BK050006 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:ACP 215
Glycerolization/Deglycerolization
System
Cleared Date: 14-APR-2005
- BK050047 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:MCS+9000, SDP revision E software,
994CF-CPP series disposable sets
Cleared Date: 21-NOV-2005
- BK050048 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics MCS+ 8150 Apheresis
System
Cleared Date: 27-SEP-2005
- BK060008 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics ACP 215
Glycerolization/Deglycerolization
System
Cleared Date: 23-MAY-2006

BK060023 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics MCS+ 8150 Apheresis
System
Cleared Date: 23-MAY-2006

BK060033 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics PCS 2 Plasma
Collection System, Wireless (W)
Capable Modification-
Cleared Date: 27-MAR-2008

BK060057 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Cymbal Automated Blood Collection
System
Cleared Date: 28-FEB-2007

BK070019 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Haemonetics PCS2 Plasma Collection
System
Cleared Date: 23-MAY-2007

BK080001 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9144
Trade Name:PCS2 Plasma Collection
System_Revision K software
Cleared Date: 28-MAY-2008

BK080025 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Cymbal Automated Blood Collection
System
Cleared Date: 15-AUG-2008

BK080038 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9144
Trade Name:MCS+ 9000 System
Cleared Date: 04-SEP-2008

BK090004 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9144
Trade Name:MCS+8150 System - Wireless
Cleared Date: 20-FEB-2009

BK090041 Haemonetics Corporation
400 Wood Road

Braintree, MA 02184-9114
Trade Name:Symphony System
Cleared Date: 28-SEP-2009

BK090083 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Cymbal Automated Blood Collection
System
Cleared Date: 27-JAN-2010

BK110015 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name:Nextgen - 1.0.0
Cleared Date: 13-JUN-2011

BK120002 Haemonetics Corporation
10025 - 102A Avenue
Suite 500
Edmonton, Alberta Canada T5J 272
Trade Name:LOGIC version 3.0.0
Cleared Date: 24-APR-2012

BK000037 Harvest Technologies
40 Grissom Road
Plymouth, MA 02360
Trade Name:Harvest PRP Separation System
Cleared Date: 05-FEB-2001

BK100059 Harvest Technologies
40 Grissom Road
Plymouth, MA 02360
Trade Name:Harvest PRP Separation System
Cleared Date: 18-NOV-2010

BK050001 Healthcare Management Systems, Inc.
3102 West End Avenue, Suite 400
Nashville, TN 37203
Trade Name:Monitor Blood Administration
Module - Release 24.0
Cleared Date: 28-SEP-2005

BK090025 Healthcare Management Systems, Inc.
3102 West End Avenue, Suite 400
Nashville, TN 37203
Trade Name:HMS Blood Administration Module,
Release 8.0
Cleared Date: 04-MAR-2010

BK030049 Healthcare-ID
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name:Donor-ID - version 2.5
Cleared Date: 31-OCT-2003

BK060058 Healthcare-ID

1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name:Donor-ID - 3.0
Cleared Date: 08-FEB-2007

BK080044 Healthcare-ID
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name:Donor-ID Web - 3.1.4
Cleared Date: 10-JUN-2009

BK120030 Healthcare-ID
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name:Donor-ID Web (TM) 3.2
Cleared Date: 25-JUN-2012

BK820013 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:Platelet Agitator
Cleared Date: 29-OCT-1982

BK820022 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:Helmer Incubator-Agitator
Cleared Date: 03-JAN-1983

BK840027 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:Helmer Platelet Agitator PF108
Helmer Platelet Agitator PF54
Cleared Date: 16-APR-1985

BK850014 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:PLATELET FLATBED AGITATOR MODEL
PF456
Cleared Date: 30-AUG-1985

BK850015 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:Helmer Incubator Models PC1000
Helmer Incubator Models PC2000
Helmer Incubator Models PC3000
Cleared Date: 20-SEP-1985

BK850018 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:Tube Stripper
Cleared Date: 21-OCT-1985

BK940051 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name:Helmer Water Plasma Thawer
Cleared Date: 03-MAR-1995

BK020029 Helmer Labs., Inc.
15425 Herriman Boulevard
Noblesville, IN 46060
Trade Name:UltraCW (with Software version
3.13)
Cleared Date: 04-OCT-2002

BK890028 Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
Trade Name:Olympus PK CMV System
Cleared Date: 11-DEC-1989

BK940035 Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
Trade Name:Olympus PK TM CMV System & System
Controls
Cleared Date: 15-JUL-1996

BK950008 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name:LeukoNet Pre Storage
Leukodepletion Filtration System
Cleared Date: 28-JUN-1995

BK980014 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name:HemaSure r|LS Pre-Storage
Leukoreduction Filtration System
for Red Blood Cells
HemaSure r|LS Pre-Storage
Leukoreduction Filtration System
with spike for Red Blood Cells
Cleared Date: 27-MAY-1999

BK070024 Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name:LEUKOSEP® HRC-600-C Leukocyte
Reduction Filtration System for
Red Blood Cells
Cleared Date: 23-AUG-2007

BK080031 Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name:HEMERUS LEUKOSEP HRC-600-C
Leukocyte Reduction Filtration

System for Red Blood Cells
Cleared Date: 11-SEP-2008

BK060048 HemoCue AB
Kuvettgatan 1
Angelholm, Sweden SE-262 71
Trade Name:HemoCue Hb 301 System
Cleared Date: 05-OCT-2006

BK000043 HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name:HemoCue Low Hemoglobin Analyzing
System
Cleared Date: 09-APR-2001

BK030020 HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name:Donor Hemoglobin Checker System
Cleared Date: 17-APR-2003

BK030067 HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name:HemoCue Donor Hb Checker Control
Cleared Date: 19-DEC-2003

BK040031 Hemosystem, S.A.
45, Cours Gouffe
13006 Marseille, France
Trade Name:Scansytem bacterial detection
device
Cleared Date: 23-SEP-2004

BK900024 Heraeus Inc.
111A Corporate Blvd, S.
Plainfield, NJ 07080
Trade Name:Cryofuge 6000
Cleared Date: 05-NOV-1992

BK900015 I. B. G. Systems Inc.
P.O. Box 5306
Laytonsville, MD 20882
Trade Name:Inverness Blood Grouping System
Cleared Date: 20-SEP-1990

BK920019 I. B. G. Systems Inc.
P.O. Box 5306
Laytonsville, MD 20882
Trade Name:Inverness Automated Antibody
Screening System
Cleared Date: 26-MAR-1993

BK930025 ICU MEDICAL INC
142 TECHNOLOGY DRIVE
IRVINE, CA 92718

Trade Name:Kelsea Clamp Needle Cover & Guide
Cleared Date: 28-OCT-1993

BK030087 ITL Corporation Pty, Ltd
41-45 Tennant Street
Canberra ACT 2609, Australia
Trade Name:ITL SampLok Sampling Kit
Cleared Date: 18-FEB-2004

BK980008 ITL Corporation, LTD.
22 Molonglo Mall
Fyshwick, Canberra Australia 2609
Trade Name:Bloodpack Needle Protector (BNP)
Cleared Date: 07-APR-1998

BK820010 Idas America Ltd.
Lockview Plaza
Lockport, NY 14094
Trade Name:Animec
Cleared Date: 14-SEP-1982

BK820019 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Checkcell
Cleared Date: 15-DEC-1982

BK830004 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:22% Bovine Albumin
Cleared Date: 17-MAR-1983

BK830005 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:30% Bovine Albumin
Cleared Date: 17-MAR-1983

BK830007 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Low Ionic Strength Solution (LISS)
Cleared Date: 11-MAY-1983

BK830013 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Rh-Hr Control
Cleared Date: 19-JUL-1983

BK830021 Immucor, Inc.

3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Anti-N Lectin
Cleared Date: 07-NOV-1983

BK830022 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ImmuAdd
Cleared Date: 07-NOV-1983

BK830018 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Anti-A1 Lectin
Cleared Date: 07-NOV-1983

BK840024 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:corQc Test System
Cleared Date: 08-NOV-1984

BK860017 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture P Solid Phase System
Cleared Date: 06-OCT-1986

BK880010 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R (I and II)
Cleared Date: 03-JUN-1988

BK880011 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R (Pooled)
Cleared Date: 03-JUN-1988

BK880014 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Modified Capture-P
Cleared Date: 08-DEC-1988

BK880015 Immucor, Inc.
3130 Gateway Drive

P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-P Platelets Wash & Storage
Solution
Cleared Date: 08-DEC-1988

BK880022 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture P Ready Screen Solid Phase
Assay
Cleared Date: 03-MAY-1989

BK890012 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture- R Ready- Screen (Pooled)
Cleared Date: 21-JUN-1990

BK890013 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R Ready-Screen (I&II)
Cleared Date: 21-JUN-1990

BK890014 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R Ready-Id
Cleared Date: 21-JUN-1990

BK890022 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Ficin Solution Reagent Set
Cleared Date: 26-JAN-1990

BK920033 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:pHix
Cleared Date: 21-SEP-1993

BK950017 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture S
Cleared Date: 24-OCT-1997

BK950029 Immucor, Inc.

3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture - CMV
Cleared Date: 22-DEC-1995

BK960016 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Hemagglutination/Dilution Strips
Cleared Date: 04-JUN-1997

BK960017 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Modified Capture-R
Cleared Date: 30-JUN-1998

BK960018 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ABS QC Test System/ABS QC Test
System Plus
Cleared Date: 21-JUL-1997

BK960019 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ABS2000
Cleared Date: 30-JUN-1998

BK960020 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture -R Control Cells
Cleared Date: 04-JUN-1997

BK000021 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-S Solid Phase Assay
Cleared Date: 22-JUN-2000

BK000024 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ABS2000, Version 2 software
(2.05.00A and 2.05.00B)
Cleared Date: 03-JUL-2001

BK010002 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ABS2000 (version 1.00.30A SR-1)
Cleared Date: 16-FEB-2001

BK010020 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ABS2000 with Version 2.05.00A
Software
ABS2000 with Version 2.05.00B
Software
ABS2000 with Version1.00.30A SR-2
Software
Cleared Date: 24-SEP-2001

BK020053 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R Ready Indicator Red
Cells
Cleared Date: 27-JAN-2003

BK020054 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R Control Cells
Cleared Date: 27-JAN-2003

BK040010 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Monoclonal Control
Cleared Date: 23-APR-2004

BK040013 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo version 1.3.6 SP4
Cleared Date: 23-APR-2004

BK040014 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo QC Cell
Cleared Date: 22-APR-2004

BK040023 Immucor, Inc.
3130 Gateway Drive

P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:DAT Positive Control Cell
Cleared Date: 23-APR-2004

BK040024 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-R Select Solid Phase
System
Cleared Date: 28-APR-2004

BK040057 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Check cell (Weak)
Cleared Date: 06-OCT-2004

BK050050 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Capture-CMV
Galileo Automated Blood Bank
System
Cleared Date: 14-NOV-2005

BK060009 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo Automated Blood Bank
System with Capture-S Syphilis
Screening Assay
Cleared Date: 11-APR-2006

BK060016 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:corQC Test System
Cleared Date: 09-MAY-2006

BK070013 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Monoclonal Control
Cleared Date: 14-JUN-2007

BK070014 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:DAT Positive Control Cell

Cleared Date: 14-JUN-2007

- BK070015 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:WB corQC
Cleared Date: 14-JUN-2007
- BK070016 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo Echo Automated Blood Bank
System
Cleared Date: 14-JUN-2007
- BK070039 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:corQC Extend
Cleared Date: 28-SEP-2007
- BK070040 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo Automated Blood Bank
System with assays to perform red
blood cell phenotyping
Cleared Date: 28-SEP-2007
- BK070051 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Immucor's WB corQC
Cleared Date: 16-NOV-2007
- BK070054 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo with Reverse ABO Group
Assay
Cleared Date: 30-NOV-2007
- BK080070 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Automated Blood Bank Analyzer
Cleared Date: 05-FEB-2009
- BK090057 Immucor, Inc.
3130 Gateway Drive

P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo
Cleared Date: 09-JUL-2010

BK100001 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo Neo
Cleared Date: 29-APR-2010

BK100033 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Galileo Neo
Cleared Date: 23-AUG-2010

BK110050 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:Checkcell
Cleared Date: 03-OCT-2011

BK110067 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:FMH RapidScreen
Cleared Date: 22-MAY-2012

BK120016 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name:ImmuLINK, version 2.0
Cleared Date: 14-JUN-2012

BK110054 Immunetics, Inc.
27 Drydock Avenue
Boston, MA 02210-2377
Trade Name:BacTx(R) Bacterial Detection Kit
for Platelets
Cleared Date: 11-JUN-2012

BK910033 In-Touch Company
101 N 700 West
Salt Lake City, UT 84954
Trade Name:Alton Dean Model 537 Blood Warmer
Cleared Date: 18-NOV-1992

BK960068 Indico, Inc.
Suite 137
6325 103 Street
Edmonton, ALBERTA Canada T6H 5H6

Trade Name:RadTag
Cleared Date: 30-OCT-1996

BK000008 Indico, Inc.
Suite 137
6325 103 Street
Edmonton, ALBERTA Canada T6H 5H6
Trade Name:RadTag
Cleared Date: 01-MAR-2000

BK950064 Informatics
4000 Kruso Way Place
Building 3 Suite 210
Lake Oswego, OR 97035
Trade Name:Lifeline Blood Bank Data
Management System, Release 4.2
Cleared Date: 01-JUL-1998

BK950032 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Abbott Data Management System,
version 3.0.2
Cleared Date: 18-AUG-1998
Cleared Under Abbott Laboratories

BK950037 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Components& Distribution
Information System (CDIS)
Cleared Date: 26-AUG-1996

BK950045 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:DONOR MANAGEMENT INFORMATION
SYSTEMS
Cleared Date: 26-AUG-1996

BK980020 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Plasma Center Management System -
Version 1.0
Cleared Date: 31-JUL-1998

BK980028 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:PCMS - version 1.1
Cleared Date: 04-SEP-1998

BK990016 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Surround System - 1.0

Cleared Date: 27-AUG-1999

BK990029 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Plasma Center Management System
(PCMS) Version 1.2
Cleared Date: 13-OCT-1999

BK000016 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Information Data Management
Surround System - 2.0
Cleared Date: 07-APR-2000

BK990046 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Plasma Center Management System
(PCMS) - Version 2.0
Cleared Date: 06-JAN-2000

BK010028 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:IDM Surround System - 3.0
Cleared Date: 05-SEP-2001

BK020038 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:Surround System, Version 3.2
Cleared Date: 08-OCT-2002

BK050014 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:IDM Prelude System, Version 1.1
Cleared Date: 18-JUL-2005

BK070031 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name:IDM Symphony System - 2.0
Cleared Date: 13-DEC-2007

BK860042 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name:Insta Cool Model BP2502
Cleared Date: 04-MAR-1987

BK900032 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name:MP III

Cleared Date: 30-MAR-1992

BK910011 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name:MT-200 FROZEN PLASMA THAWER
Cleared Date: 19-DEC-1991

BK940019 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name:Hemopharm PB-500 Pocket Sealer
Cleared Date: 26-SEP-1994

BK850016 Integrated Diagnostics, Inc.
1901 Sulphur Spring Road
Baltimore, MD 1227
Trade Name:HLA COMPREHENSIVE TRAY
Cleared Date: 30-DEC-1985

BK870018 Integrated Diagnostics, Inc.
1901 Sulphur Spring Road
Baltimore, MD 1227
Trade Name:INDX HLA-DR, DQ Lymphocyte
Phenotyping Tray
Cleared Date: 28-OCT-1987

BK080006 IntellidOT Corporation
13520 Evening Creek Drive North,
Suite 400
San Diego, CA 92128
Trade Name:IntellidOT Blood Product
Administration
Cleared Date: 13-JUN-2008

BK820001 International Business Machines

Princeton, NJ 08540
Trade Name:IBM 2991
Cleared Date: 28-JUN-1982

BK830003 International Business Machines

Princeton, NJ 08540
Trade Name:IBM 2991 - Single Unit Leukocytes
from Whole Blood
Cleared Date: 27-MAY-1983

BK830020 International Business Machines

Princeton, NJ 08540
Trade Name:Plastic for 2997
Plastic for 2991
Cleared Date: 27-OCT-1983

BK830024 International Business Machines

Princeton, NJ 08540
Trade Name:Plastic for 2991
Plastic for 2997
Cleared Date: 09-MAR-1984

BK820020 International Equipment Company
300 Second Avenue
Needham Heights, MA 02194
Trade Name:IEC Centra-W Cell Washer
Cleared Date: 05-APR-1983

BK940004 International Equipment Company
300 Second Avenue
Needham Heights, MA 02194
Trade Name:Seromax
Cleared Date: 08-APR-1994

BK910018 International Specialty Products
1361 Alps Road
Wayne, NJ 07470
Trade Name:RAD-SURE BLOOD IRRADIATION LABEL
Cleared Date: 12-MAR-1992

BK920035 International Specialty Products
1361 Alps Rd,
Wayne, NJ 07470
Trade Name:RAD-Sure 2500
Cleared Date: 01-APR-1993

BK070038 Invitrogen Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name:AllSet Gold SSP
Cleared Date: 26-SEP-2007

BK070041 Invitrogen Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name:DynaChip HLA Antibody Analysis
System
Cleared Date: 30-APR-2008

BK070046 Invitrogen Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name:UniMatch Plus Version 4.0
Cleared Date: 27-SEP-2007

BK960054 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name:Jewett Models BPL13,BPL21,BPL25
Cleared Date: 08-AUG-1996

BK960073 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098

Trade Name:Models BBR17, BBR25, BBR37 & BBR55
Cleared Date: 30-OCT-1996

BK960089 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name:Jewett Model CT1
Cleared Date: 06-FEB-1997

BK970001 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name:Jewett Model CTF-1
Cleared Date: 16-APR-1997

BK970014 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name:Jewett Model BBWM3
Cleared Date: 18-JUL-1997

BK970028 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name:Jewett Model BPL55
Cleared Date: 15-OCT-1997

BK860037 Jouan, Inc.
Route 8, Box 1202; P.O. Box 2716
Winchester, VA 22601
Trade Name:Model LR5.22 centrifuge
Cleared Date: 15-DEC-1986

BK870001 Jouan, Inc.
Route 8, Box 1202; P.O. Box 2716
Winchester, VA 22601
Trade Name:Model GR 4.11 centrifuge
Cleared Date: 20-FEB-1987

BK890027 Jouan, Inc.
Route 8, Box 1202; P.O. Box 2716
Winchester, VA 22601
Trade Name:Model KR4-22 Centrifuge
Cleared Date: 02-FEB-1990

BK080057 Kaylight Corporation
602 Anacapa
Irvine, CA 92602
Trade Name:My Cells Autologous Platelet
Preparation Kit
Cleared Date: 25-SEP-2009

BK840005 Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name:Kontron Microgroupamatic
Cleared Date: 27-JUN-1984

BK870012 Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name:LHS-500 Sampler and Delivery
System
Cleared Date: 02-NOV-1987

BK890008 Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name:G-1000
G-2000
G-2000 MK II
Cleared Date: 30-AUG-1989

BK040053 Korchek Technologies, LLC
770 Plattsville Road
Trumbull, CT 06611
Trade Name:CareChek Patient Identification
System, CareChek TX - version 1
Cleared Date: 12-AUG-2005

BK030037 Kowa Company, Ltd.
c/o Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852
Trade Name:LD-2000 Leukocyte Counter
Cleared Date: 14-JUN-2004

BK100024 Lab 21 Healthcare Ltd
184 Cambridge Science Park
Cambridge, Cambridgeshire United
Kingdom CB4 0GA, UK
Trade Name:Lab 21 TPHA OC Kit
Cleared Date: 03-AUG-2010

BK860031 Lab-Line Instruments, Inc.
15th and Bloomingdale Avenues
Melrose Park, IL 60160
Trade Name:Hema-Bath
Cleared Date: 02-MAR-1987

BK110055 Lattice, Inc.
1751 South Naperville Rd
Suite 100
Wheaton, IL 60189
Trade Name:MediCopia Transfusion - v4.1
Cleared Date: 06-JAN-2012

BK860023 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name:Level 1 Fluid Warmer
Cleared Date: 25-SEP-1986

BK920021 Level 1 Technologies, Inc.

160 Weymouth Street
Rockland, MA 02370
Trade Name:A/V Rewarming Procedural Kit
Gentilello Technique
Cleared Date: 29-JAN-1993

BK940056 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name:Level I Fluid Warmer
Cleared Date: 27-DEC-1994

BK020043 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name:level 1 fluid warming system
Cleared Date: 16-JUN-2003

BK080017 LifeSouth Community Blood Centers Inc.
4039 W. Newberry Road
Gainesville, FL 32607
Trade Name:Integrated Blood Bank Information
System (IBBIS) Registration Module
- v1.0
Cleared Date: 05-AUG-2008

BK090064 LifeSouth Community Blood Centers Inc.
4039 W. Newberry Road
Gainesville, FL 32607
Trade Name:Integrated Blood Bank Information
System
Cleared Date: 08-DEC-2009

BK830006 Liquid Crystal Products, Inc.
724 Algonquin Road
Arlington Heights, IL 60005
Trade Name:HemoTemp II Blood Temperature
Indicator
Cleared Date: 04-MAY-1983

BK990013 Ljungberg & Kogel
C/O Kamm & Associates
333 Milford Rd.
Deerfield, IL 60015
Trade Name:Biomixer 330 & Biomixer 323
Cleared Date: 07-JUL-1999

BK090010 Ljungberg & Kogel
C/O Kamm & Associates
333 Milford Rd.
Deerfield, IL 60015
Trade Name:Biomixer BM330 with XBee
(Wireless) Option
Cleared Date: 17-JUL-2009

BK960050 MAK-System
Z.I. Paris Nord II

14, Rue de la Perdrix
95946 Roissy C.D.G. CEDEX, France
B.P. 50035

Trade Name:Progesa
Cleared Date: 10-DEC-1998

BK060035 MAK-System
10 Avenue de la Grande Armee
75017 Paris, France 75017
Trade Name:Patient Health Software - 1.0
Cleared Date: 09-MAY-2007

BK070062 MAK-System
10 Avenue de la Grande Armee
75017 Paris, France 75017
Trade Name:PROGESA - 4.4h
Cleared Date: 26-OCT-2007

BK080002 MAK-System
10 Avenue de la Grande Armee
75017 Paris, France 75017
Trade Name:ePROGESA - 5.0.1
Cleared Date: 13-MAY-2008

BK960029 MEDITECH Medical Information Technology,
Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name:MEDITECH
Cleared Date: 19-MAR-1999

BK980046 MEDITECH Medical Information Technology,
Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name:Magic Client Server - 5.1
Cleared Date: 08-FEB-2000

BK060029 MEDITECH Medical Information Technology,
Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name:MEDITECH MAGIC Blood Bank Software
- 4.9
Cleared Date: 06-FEB-2007

BK080037 MEDITECH Medical Information Technology,
Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name:MEDITECH Client Server Blood bank
module 5.6 - v5.6
Cleared Date: 30-OCT-2008

BK080061 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214

Trade Name:HCLL Donor
Cleared Date: 02-DEC-2008

BK100043 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name:LifeTrak/Donor - 4.6.0
Cleared Date: 21-OCT-2010

BK100057 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name:LifeTrak/Lab and Distribution -
4.6.0
Cleared Date: 16-NOV-2010

BK100069 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name:LifeTrak/Plasma - 1.0.0
Cleared Date: 04-MAR-2011

BK970040 MEDSEP Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Medsep Plasma Bag
Cleared Date: 23-JAN-1998
Cleared Under MEDSEP Corp.

BK980027 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name:Transfer/Freezing Bag Set
Cleared Date: 26-MAR-1999
Cleared Under MEDSEP Corp.

BK980030 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name:Medsep Freezing bag
Cleared Date: 29-AUG-1998
Cleared Under MEDSEP Corp.

BK980038 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name:Cell Wash/Infusion Bag Set
Cleared Date: 13-JUL-1999
Cleared Under MEDSEP Corp.

BK000032 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name:Modified Plasma Bag
Cleared Date: 27-SEP-2000
Cleared Under MEDSEP Corp.

BK050015 MEDSEP Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Leukotrap SC RC Filtration System
Cleared Date: 14-APR-2005
Cleared Under MEDSEP Corp.

BK080003 MEDSEP Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall Acrodose PLus System,
Platelet Pool and Store Set with
in-Line Leukocyte Reduction Filter
Cleared Date: 18-APR-2008

BK120026 MEDSEP Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall Celeris fPC System
Cleared Date: 29-JUN-2012

BK930021 MIGADAS INC
482 Hudson Terrace
Englewood Cliffs, NY 07632
Trade Name:Samplink
Cleared Date: 16-NOV-1993

BK970022 MIGADAS INC
482 Hudson Terrace
Englewood Cliffs, NY 07632
Trade Name:samplink
Cleared Date: 18-SEP-1997

BK910007 MMED
609 19th Avenue, S.W.
Rochester, MN 55902
Trade Name:MMED Vapor Condensation Blood
Warmer
Cleared Date: 16-MAR-1992

BK910004 MPI/Dupaco, Inc.
2620 Temple Heights Drive
Oceanside, CA 92056
Trade Name:Dupaco Blood/Fluid Warming Cuff
Set
Cleared Date: 21-FEB-1992

BK030008 MacoProductions S.A.S.
c/o Hoppe Regulatory Consultants
2335 massey Lane
Decatur, GA 30033
Trade Name:Leucolab LCG2 Leukoreduction
System for Red Blood Cells
Cleared Date: 02-MAY-2003

BK050041 MacoProductions S.A.S.
c/o Hoppe Regulatory Consultants

2335 massey Lane
Decatur, GA 30033
Trade Name:Leucolab LCG2 Leukoreduction
System for Red Blood Cells
Cleared Date: 12-OCT-2005

BK080060 MacoProductions S.A.S.
1733 Canton Lane
Suite 103
Marietta, GA 30062-2679
Trade Name:Leucolab LCG2 Leukoreduction
System for AS-1, AS-3, and AS-5
Red Blood Cells
Cleared Date: 14-JAN-2009

BK960075 Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
St. Louis, MO 63134
Trade Name:Alton Dean Fluid Warmer, FW-537
Cleared Date: 28-FEB-1997

BK090051 McKesson Provider Technologies
5995 Windward Parkway
Alpharetta, GA 30005
Trade Name:Horizon MobileCare Transfusion
Cleared Date: 28-MAY-2010

BK920031 Medical Marketing Consultants
3 Bethesda Metro Center,Suite 750
Bethesda, MD 20814
Trade Name:sHLA-STAT B27 ELISA for HLA-B27
Typing
Cleared Date: 20-AUG-1993

BK980034 Medware Information Systems, Inc.
1121 Old Walt Whitman Road
Melville, NY 11747
Trade Name:Hemocare Blood Bank Management
System - Revision 5.2
Cleared Date: 10-DEC-1998

BK010052 Medware Information Systems, Inc.
9000 Harry Hines Blvd
Dallas, TX 75235
Trade Name:LifeTrak Lab - 2.03
Cleared Date: 17-JUN-2002

BK020046 Medware Information Systems, Inc.
900 Oakmont Lane
Westmont, IL 60659
Trade Name:Hemocare LifeLine - Version, 1.0
Cleared Date: 14-FEB-2003

BK030078 Medware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name:HCLL - 2.6

Cleared Date: 08-APR-2004

BK040047 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name:Instrument Interface Engine - 1.0
Cleared Date: 16-JUL-2004

BK050011 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name:HCLL Donor - 1.0
Cleared Date: 10-MAY-2005

BK060019 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name:Life Trak / Donor - 3.01
Cleared Date: 21-JUN-2006

BK080049 Mediware Information Systems, Inc.
1900 Spring Road, Suite 450
Oak Brook Service Center
Oak Brook, IL 60523
Trade Name:HCLL Transfusion, v3.0
Cleared Date: 22-OCT-2008

BK910019 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289
Trade Name:Pall BPF4B Leukocyte Removal Blood
Processing Filter wiht Attached
Tubing and Blood Bag
Cleared Date: 16-JAN-1992
Cleared Under Pall Bio Medical

BK920023 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289
Trade Name:Pall Autostop Leukocyte Removal
Platelet Filter with Tubing
Cleared Date: 26-OCT-1992
Cleared Under Pall Bio Medical

BK940018 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289
Trade Name:Pall AutoprocessorTM System
Cleared Date: 07-SEP-1994
Cleared Under Pall Bio Medical

BK020014 Medsep Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall Bacterial Detection System
(BDS)
Cleared Date: 22-OCT-2002

BK030082 Medsep Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall eBDS
Cleared Date: 04-FEB-2004

BK050034 Medsep Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall Acrodose™ PL System, Platelet
Pool and Store Set with eBDS
Pall Platelet Pool and Store Set
with Pall eBDS
Cleared Date: 28-SEP-2005

BK050074 Medsep Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall Acrodose PL System
Cleared Date: 26-JAN-2006

BK050075 Medsep Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall eBDS
Cleared Date: 20-DEC-2005

BK060040 Medsep Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall Acrodose PL System, Platelet
Pool and Store Set with in-line
Leukocyte Reduction Filter
Cleared Date: 12-APR-2007

BK060044 Medsep Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall Acrodose™ PL System, Platelet
Pool and Store Set with eBDS
Cleared Date: 01-SEP-2006

BK060045 Medsep Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall Acrodose™ PL System, Platelet
Pool and Store Set
Cleared Date: 01-SEP-2006

BK060047 Medsep Corporation
16 Pepperwood Lane
Pepper Pike, OH 44124
Trade Name:Pall eBDS
Cleared Date: 04-APR-2007

BK070004 Medsep Corporation

1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall eBDS
Cleared Date: 26-JUN-2007

BK070056 Medsep Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall Acrodose PPlus System Platelet
Pool and Store Set with in-line
Leukocyte Reduction Filter and
eBDS
Cleared Date: 27-SEP-2007

BK070057 Medsep Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall Acrodose PPlus System Platelet
Pool and Store Set with in-line
Leukocyte Reduction Filter
Cleared Date: 27-SEP-2007

BK070063 Medsep Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name:Pall eBDS
Cleared Date: 26-JAN-2008

BK090007 Medsep Corporation
1630 INDUSTRIAL PARK
COVINA, CA 91722
Trade Name:Pall Acrodose PL System
Cleared Date: 25-FEB-2009

BK100058 Medsep Corporation
1630 INDUSTRIAL PARK
COVINA, CA 91722
Trade Name:The Pall Celeris fPC System
Cleared Date: 24-FEB-2011

BK010032 Medserv, Inc.
71 South Bedford Road
Mount Kisco, NY 10549
Trade Name:Plasmapheresis Data System III -
1.0
Cleared Date: 05-FEB-2002

BK030040 Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Trade Name:Magellan Autologous Platelet
Separation System
Cleared Date: 03-SEP-2003

BK040068 Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

Trade Name:Magellan Autologous Platelet
Separator System
Cleared Date: 09-NOV-2004

BK940010 Mercia Diagnostics Limited
Mercia House, Broadford Park
Shalford, Guildford GU4 8EW, United
Kingdom
Trade Name:CAPTIA TM Syphilis-G
Cleared Date: 03-JAN-1995

BK920004 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MGR Model ERB-5-0378
Cleared Date: 12-MAR-1992

BK920013 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Diluent 2
Cleared Date: 29-SEP-1993

BK920014 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Centrifuge
Cleared Date: 29-SEP-1993

BK920016 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Buffered Gel Card
Cleared Date: 29-SEP-1993

BK920030 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Diluent 1
Cleared Date: 29-SEP-1993

BK930030 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Diluent 2 Plus
Cleared Date: 12-JAN-1994

BK940034 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Control Card
Cleared Date: 27-JUL-1994

BK950025 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Incubator

Cleared Date: 08-MAY-1995

BK950026 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Work Table
Cleared Date: 15-MAY-1995

BK950027 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:ID-Pipetor
Cleared Date: 01-JUN-1995

BK950028 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Dispenser (0.5ml and 1.0ml)
Cleared Date: 27-JUN-1995

BK960013 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS-Centrifuge Model NU 9310
Cleared Date: 15-APR-1996

BK980016 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:ID-Tipmaster
Cleared Date: 29-OCT-1998

BK990012 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Reader M
Cleared Date: 19-NOV-1999

BK000018 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Reader SA
Cleared Date: 21-NOV-2000

BK010021 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:MTS Incubator II
Cleared Date: 01-OCT-2001

BK030023 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:Ortho ProVue, Software Version:
2.10
Cleared Date: 14-MAY-2003

BK090013 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:ORTHO ProVue, version 3.1
Cleared Date: 04-JUN-2009

BK110029 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name:Ortho ProVue Analyzer Version 3.1
Patch 1 (V3.1.1)
Cleared Date: 14-JUL-2011

BK840023 Microdrop, Incorporation
2227 Corinth Ave.
Los Angeles, CA 90064
Trade Name:Leukocyte Typing Serum Trays
Cleared Date: 12-OCT-1984

BK840013 Microdrop, Incorporation
2227 Corinth Ave.
Los Angeles, CA 90064
Trade Name:Lambda Cell Tray
Cleared Date: 20-NOV-1984

BK100008 Micronics
8463 154th Avenue NE
Redmond, WA 98052
Trade Name:ABORhCard
Cleared Date: 30-APR-2010

BK910034 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name:QWIK-1 Bld. and Plasma Warmer
Cleared Date: 29-JUL-1993

BK940003 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name:Qwik - 1 TM - 500
Cleared Date: 24-FEB-1994

BK970044 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name:ThermoStat 900
Cleared Date: 23-JAN-1998

BK970045 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name:ThermoStat 900 Blood & IV Fluid
Adm. Set
Cleared Date: 06-MAR-1998

BK850026 Miles, Inc.

4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:Neocel System
Cleared Date: 22-MAY-1986

BK860006 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:Cutter PPP Harness
Cleared Date: 17-SEP-1986

BK860016 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:PENTEX MOD-U-CYTE II & VIII
Cleared Date: 17-APR-1987

BK860028 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:Component Aliquot System
Cleared Date: 07-DEC-1987

BK900034 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:Phlebotomist Protection Device
Cleared Date: 27-JAN-1992

BK920027 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:Plasma Pooling Bag
Cleared Date: 13-APR-1993

BK930001 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name:Plasma Sample Vial
Cleared Date: 20-SEP-1993

BK090020 Miltenyi Biotec, Inc.
120 Presidential Way
Suite 305
Woburn, MA 01801
Trade Name:CryoMACS Freezing Bag
Cleared Date: 13-JAN-2010

BK030065 Mississippi Blood Services, Inc.
1995 Lakeland Drive
Jackson, MS 39216
Trade Name:WebLab Online Laboratory System -
2.0
Cleared Date: 22-DEC-2003

BK040065 Misys Healthcare Systems
4801 East Broadway Boulevard

Tucson, AZ 85711
Trade Name: Misys Laboratory Blood Bank and
Blood Donor - 6.0.1
Cleared Date: 22-OCT-2004

BK060014 Mosum Technology India PVT LTD
55 Northern Blvd, Suite 200
Great Neck, NY 11021
Trade Name: PowerBANK Enterprise Edition -
version 1.0
Cleared Date: 30-MAR-2007

BK920024 Murex Biologicals, Inc.
1107 I-45 South
Conroe, TX 77301
Trade Name: Murex PEG Potentiator for Antibody
Detection
Cleared Date: 01-JUN-1993

BK910016 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Compomat
Cleared Date: 30-MAR-1992

BK930018 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Blood Collection Mixer MW 5001
Cleared Date: 24-JUL-1994

BK930020 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Biotrans Separator
Cleared Date: 27-JUL-1994

BK940061 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Composeal Mobile and Composeal
Universal
Cleared Date: 26-JAN-1995

BK950035 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Compocool
Cleared Date: 27-SEP-1995

BK960084 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Gambro Hemofreeze Bag
Cleared Date: 28-MAY-1998

BK940053 Nanoentek, Inc.

300 Washington St., STE 416
Newton, MA 02458
Trade Name:Olympus PK System
Cleared Date: 29-NOV-1995
Cleared Under Schiff & Company

BK120015 Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name:ADAM-rWBC
Cleared Date: 24-JUL-2012

BK950042 National Hospital Specialties
104 Johnson Avenue
Hackensack, NJ 07601
Trade Name:Genesis Blood Collection Mixer
Cleared Date: 19-SEP-1995

BK840016 Neocyte
199 Weymouth Street
Rockland, MA 02370
Trade Name:NEOPACK System
Cleared Date: 25-JUN-1985

BK050032 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia Canada
V6H 1C3
Trade Name:BloodTrack SafeTx - Version 2.0
Cleared Date: 16-AUG-2005

BK050059 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia Canada
V6H 1C3
Trade Name:BloodTrack Courier - 3.2
Cleared Date: 13-DEC-2005

BK060041 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia Canada
V6H 1C3
Trade Name: BloodTrack - 4.1
Cleared Date: 12-OCT-2006

BK920020 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name:NSBR211,NSBR482,and NSB763 Blood
Refrigerators
Cleared Date: 19-JAN-1993

BK930002 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name:NSBR61 (Nor-Lake Scientific Blood
Bank, 6ft Single Door)

Cleared Date: 13-APR-1995

- BK930003 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR83 (Nor-Lake Scientific Blood
Bank, 8ft Double Door)
Cleared Date: 13-APR-1995
- BK930004 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF211 (Nor-Lake Scientific
Freezers, 21ft Single Door)
Cleared Date: 13-APR-1995
- BK930005 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF482 (Nor-Lake Scientific
Plasma Freezers, 48ft Double Door)
Cleared Date: 13-APR-1995
- BK930006 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF61 (Nor-Lake Scientific Plasma
Freezer, 6ft Single Door)
Cleared Date: 13-APR-1995
- BK900023 North American Biologicals, Inc.
16500 N.W. 15th Avenue
Miami, FL 33169
Trade Name: QC-HIV
Cleared Date: 13-NOV-1991
- BK910006 North American Biologicals, Inc.
16500 N.W. 15th Avenue
Miami, FL 33169
Trade Name: QC-Hepatitis
Cleared Date: 12-MAR-1992
- BK920015 North American Biologicals, Inc.
16500 N.W. 15th Avenue
Miami, FL 33169
Trade Name: VirocheQC 1
Cleared Date: 20-MAY-1993
- BK910028 North American Technical Services Corp.
407 E Main St.
Port Jefferson, NY 11777
Trade Name: ASTOTHERM/ASTOTUBE
Cleared Date: 13-JUL-1992
- BK110060 Novartis Vaccines and Diagnostics, Inc.
4560 Horton St.
Emeryville, CA 94608-2916

Trade Name:PROCLEIX® NAT TRACKER® Version 3.0
Software
Cleared Date: 01-DEC-2011

- BK930023 Nu-Quest, Inc.
1031 Meadowview Drive
Webb City, MO 64870
Trade Name:Little Pig Sticker
Cleared Date: 24-FEB-1994
- BK830017 Nuclear-Medical Laboratories, Division
1800 Hurd Drive
Irving, TX 75061
Trade Name:Hepa-SHure
Cleared Date: 07-OCT-1983
- BK080022 Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, Sweden
Trade Name:Olerup SSP HLA Typing Kits
Cleared Date: 20-FEB-2009
- BK090042 Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, Sweden
Trade Name:Olerup SSP HLA Typing Kits
Cleared Date: 11-SEP-2009
- BK010040 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:Olympus PK 7200 Automated
Microplate System
Cleared Date: 25-OCT-2001
- BK020024 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:Olympus PK7200 Automated
Microplate System
Cleared Date: 08-JUL-2002
- BK030009 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:Olympus PK7200 Automated
Microplate System
Cleared Date: 03-MAR-2003
- BK040003 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane

Irving, TX 75063-3104
Trade Name:Olympus PK7200 Automated
Microplate System
Cleared Date: 06-FEB-2004

BK040070 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:Tango Automated Blood Bank
Analyzer System
Cleared Date: 22-MAR-2005

BK050076 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:TANGO Automated Blood Bank
Analyzer System (HW Version 02/SW
Version 3.0)
Cleared Date: 16-DEC-2005

BK060024 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:Olympus Bromelin
Olympus PK7300 Automated
Microplate System
Olympus System Control
Cleared Date: 14-MAY-2007

BK060034 Olympus America Inc., Diagnostic Systems
Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name:TANGO Automated Blood Bank
Analyzer System
Cleared Date: 28-AUG-2006

BK090036 Olympus America Inc., Diagnostic Systems
Division
3500 Corporate Parkway
Center Valley, PA 18034
Trade Name:Olympus PK7300 Automated
Microplate System
Cleared Date: 13-JAN-2010

BK860004 Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name:Olympus PK7100
Cleared Date: 14-MAY-1986

BK870025 Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042

Trade Name:Olympus PK7100 Automated Blood
Grouping System
Cleared Date: 09-OCT-1987

- BK930024 Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name:Olympus PK7200 Blood Grouping
Analyzer
Cleared Date: 26-JAN-1994
- BK910021 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:Lifesource Flash Bag
Cleared Date: 08-JUN-1992
- BK920007 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:Lambda Monoclonal Tray Class I and
II
Cleared Date: 28-DEC-1992
- BK920009 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:Anti-B27 FITC Conjugated
Monoclonal Antibody
Cleared Date: 25-MAR-1993
- BK960011 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:Lambda Antigen Tray
Cleared Date: 03-JUL-1997
- BK960053 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:Anti-B27 FITC/CD3PE Conjugated
Monoclonal Antibody
Cleared Date: 30-OCT-1996
- BK960062 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:Micro SSP HLA Class II DNA Typing
Kit
Cleared Date: 11-FEB-1998
- BK980015 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:FlowPRA
Cleared Date: 23-JUL-1999

BK020055 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:LABTYPE SSO Typing Test
Cleared Date: 04-FEB-2003

BK030069 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Products for use with
LABScan 100 flow analyzer
Cleared Date: 31-DEC-2003

BK040049 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:LabType Visual
Cleared Date: 09-AUG-2004

BK050008 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:LABScreen Software
Cleared Date: 08-JUL-2005

BK050070 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:HLA Visual Software version 1.0
Cleared Date: 30-JAN-2006

BK050071 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:HLA Tools Software version 1.0
Cleared Date: 30-JAN-2006

BK070070 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:HLA Fusion Software v 1.0
Cleared Date: 10-MAR-2008

BK080071 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:LABScreen Multi
Cleared Date: 10-APR-2009

BK100068 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name:HNA Genotyping Trays
Cleared Date: 25-AUG-2011

BK030036 OriGen BioMedical
4020 S. Industrial Dr. #160

Austin, TX 78744
Trade Name:OriGen Cryostore Freezing Bags
Cleared Date: 01-OCT-2003

BK820003 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:ORTHO Confidence System
Cleared Date: 10-AUG-1982

BK820006 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Simwash
Cleared Date: 13-APR-1983

BK830023 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:TYTEM Typing and Detection System
Cleared Date: 08-DEC-1983

BK840017 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:ORTHO Cell Suspension Tube
Cleared Date: 16-NOV-1984

BK890021 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Ortho Confidence System
Cleared Date: 23-OCT-1989

BK920034 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Ortho BioVue System
Cleared Date: 09-MAY-1995

BK960003 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Ortho Summitt System
Cleared Date: 19-OCT-1998

BK960052 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606

Trade Name:Ortho Summit Processor
Cleared Date: 19-OCT-1998

BK990030 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Ortho Lab with Ortho Lab IC
(Instrument Concentrator)
Cleared Date: 03-APR-2000

BK050044 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Genetic Systems HIV-1/HIV-2 PLUS O
Ortho Assay Protocol Disk
Cleared Date: 03-NOV-2006

BK050046 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Genetic Systems HBsAg EIA 3.0
Ortho Assay Protocol Disk
Cleared Date: 13-JAN-2006

BK070028 Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101
Trade Name:VITROS Immunodiagnostic Products
Anti-HIV 1+2 Controls
Cleared Date: 10-APR-2008

BK090074 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Ortho Summit System
Cleared Date: 27-MAY-2009

BK100040 Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101
Trade Name:VITROS Immunodiagnostic Products
Anti-HIV 1+2 Controls
Cleared Date: 22-JUL-2010

BK100061 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:ORTHO VERSEIA™ Pipetter as part of
the ORTHO Summit™ System
Cleared Date: 28-OCT-2010

BK110026 Ortho-Clinical Diagnostics, Inc.

1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:Ortho Summit System (OSS)
Cleared Date: 28-JUN-2011

BK120006 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name:ORTHO VERSEIA Pipetter as Part of
the ORTHO Summit System (OSS) v
3.0
Cleared Date: 15-MAR-2012

BK040017 Orthogen Therapeutics, GmbH
Graf-Adolf-Str. 43
D-40210 Dusseldorf, Germany
Trade Name:Osteokin System
Cleared Date: 23-JUN-2004

BK080014 Pall Life Sciences
25 Harbor Park Drive North
Port Washington, NY 11050-4630
Trade Name:Pall eBDS
Cleared Date: 13-FEB-2009

BK820002 Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name:
Cleared Date: 06-OCT-1982

BK820023 Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name:Leukocyte Typing Serum (Human)
(Tray Package)
Cleared Date: 12-JAN-1983

BK850004 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name:Frozen Leukocyte Panel (Human)
Cleared Date: 01-AUG-1985

BK000019 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name:UniTray SSP HLA Typing Kits
Cleared Date: 29-JAN-2001

BK020068 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name:Pel Freez HLA High Resolution SSP
UniTray

Cleared Date: 14-JAN-2003

BK030003 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name:UniMatch Plus
Cleared Date: 25-FEB-2003

BK050055 Perfusion Partners & Associates, Inc.
6227 Foxfire Lane
Fort Myers, FL 33912
Trade Name:GenesisCS Component Concentrating
System
Cleared Date: 13-OCT-2006

BK900018 Polar Products, Inc.
2808 Oregon Ct. Bldg K-4
Torrance, CA 90503
Trade Name:Polar Products' Model MTE-58L
Cleared Date: 30-AUG-1990

BK060056 Prescott Ideas LLC
8960 E. Anna Place
Tucson, AZ 85710
Trade Name:Antibody Check - 4.1
Cleared Date: 23-APR-2007

BK010017 Psyche Systems Corp
Ten Laurel Avenue
Wellesley, MA 02481
Trade Name:System Blood Bank (SBB) Software -
3.0
Cleared Date: 04-SEP-2001

BK840020 Queue Systems
22 Airport Industrial Park Rd., Box
1901
Parkersburg, WV 26102
Trade Name:Cryostar
Cleared Date: 23-OCT-1984

BK990005 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name:StatusFlow Pro
Cleared Date: 21-JUN-1999

BK000035 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name:R & D Leuko-Reduced RBC Control
Cleared Date: 13-DEC-2000

BK000036 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name:R & D Leuko-Reduced Plt Control

Cleared Date: 13-DEC-2000

BK040012 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name:R&D Donor Checker Hematology
Control
Cleared Date: 05-MAR-2004

BK040063 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name:R & D Plasma Hemoglobin Hematology
Control
Cleared Date: 17-SEP-2004

BK910012 ROCHE BIOMEDICAL LABORATORIES, INC.
112 ORANGE DRIVE
ELON COLLEGE, NC 27244
Trade Name:HLA CLASS I PHENOTYPING TRAYS
Cleared Date: 06-JAN-1992

BK860034 Reagent Laboratory, Inc.
300 East Ottawa Avenue
Louisville, KY 40209
Trade Name:Sodium Chloride 1.3%
Cleared Date: 01-JUN-1987

BK090048 RegenLab SARL
3428 Avenue Marcil
Montreal, Quebec Canada H4A 2Z3
Trade Name:RegenKit-THT
Cleared Date: 18-MAY-2010

BK110061 RegenLab SARL
En Budron B2
CH-1052 Le Mont sur Lausanne
, Switzerland
Trade Name:RegenKit-BCT Family Kits
Cleared Date: 08-MAY-2012

BK880029 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name:MBF700 Blood Freezer
Cleared Date: 16-JUN-1989

BK890023 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name:HLT-20DR-87 Blood Freezer
Cleared Date: 21-SEP-1990

BK890025 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name:HLT-50V-4BB Blood Refrigerator

Cleared Date: 02-FEB-1990

BK890026 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name:REB3704 Blood Refrigerator
Cleared Date: 02-FEB-1990

BK950054 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name:Blood Storage Refrigerator REB2304
Cleared Date: 11-JAN-1996

BK950066 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name:Revco HLT 30V-4BB
Cleared Date: 31-JAN-1996

BK890006 Rexco
275 Aiken
Asheville, NC 28804
Trade Name:MBF 500 Blood Freezer
Cleared Date: 16-JUN-1989

BK020018 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton,, CA 94588-0900
Trade Name:Cobas Ampliscreen System
Cleared Date: 26-NOV-2002

BK020025 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton,, CA 94588-0900
Trade Name:COBAS AmpliScreen Data Output
Management System (DOMS) - 1.00.04
Cleared Date: 10-DEC-2002

BK110045 Rowny Systems, Inc.
7555 Spring Lake Drive
Bethesda, MD 20817-6507
Trade Name:Antigen PLUS - 7.4
Cleared Date: 25-MAY-2012

BK990008 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name:Rubin & Poor Configurable Manual
Blot System - 1.0C
Cleared Date: 29-OCT-1999

BK000030 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040

Trade Name:Configurable Laboratory Result
Manager (CLRM) - 1.0E
Cleared Date: 23-NOV-2001

BK030073 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name:Configurable Manual Batch Entry -
1.1A
Cleared Date: 14-JAN-2004

BK080028 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name:Pool results Manager
Cleared Date: 03-SEP-2008

BK050045 SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name:SoftDonor 4.3 with SoftScape
Cleared Date: 26-OCT-2005

BK060059 SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name:SoftDonor 4.4 with DMSI - 4.4
Cleared Date: 21-DEC-2006

BK080020 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name:SoftBank II - v23.2
Cleared Date: 12-AUG-2008

BK080069 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name:SoftDonor 4.5 - 4.5
Cleared Date: 16-JAN-2009

BK090017 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name:SoftBank II Version 25 - 25
Cleared Date: 23-JUN-2009

BK090078 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name:SoftID.Tx Version 1.0
Cleared Date: 28-APR-2010

BK100045 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name:SoftBank II - 25.1

Cleared Date: 29-JUL-2010

BK950057 SG Scientific
5745 SW 75th Street
#284
Gainseville, FL 32608
Trade Name:The Saber (Segment Piercing
Device)

Cleared Date: 13-NOV-1995

BK090047 SPINESMITH PARTNERS LP
93 Red River
Austin, TX 78701
Trade Name:Fusionary Graft Delivery System
Cleared Date: 10-FEB-2010

BK050052 STEMCO Biomedical, Inc.
2810 Meridan Parkway
Suite 148
Durham, NC 27713
Trade Name:Aldecourt Progenitor Cell
Enumeration Kit
Cleared Date: 02-DEC-2005

BK940017 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name:PRA-STAT Elisa/Panel React Anti-
HLA Class I IgG Antibody
Cleared Date: 27-SEP-1994

BK950009 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name:CROSS STAT
Cleared Date: 09-MAY-1995

BK970037 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name:PRA-STAT Anti-HLA CLASS I IgG
Antibodies/Two Patients per Plate
Format
Cleared Date: 18-NOV-1998

BK940011 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name:Sanguin Medusa 2000
Cleared Date: 29-SEP-1994

BK960065 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name:Sanguin Medusa 2000 - 3.4
Cleared Date: 17-DEC-1998

BK980003 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name:Aurora/Fenestra (version 1.0)
Cleared Date: 29-SEP-1999

BK980039 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name:Medusa 2000 Srimport, Version 1.2
Cleared Date: 11-JUN-1999

BK090061 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name:Sanguin Aurora version 2.0
Cleared Date: 22-DEC-2009

BK100030 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name:Sanguin Liberty SRIMPORT - 3.1
Cleared Date: 08-JUL-2010

BK010042 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name:Transwaag KL
Cleared Date: 12-DEC-2001

BK010045 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name:Sahara Blood & Plasma Warming
Device
Cleared Date: 21-DEC-2001

BK030006 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name:Transwaag Disk 01
Cleared Date: 27-FEB-2003

BK040080 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name:Sahara-TSC
Cleared Date: 09-FEB-2005

BK070029 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name:S-Monovette ACD-A
Cleared Date: 21-SEP-2007

BK940029 Scimed Life Systems, Inc.

6655 Wedgewood Rd.
Maple Grove, MN 55311
Trade Name:SCIMED UltraFuse Coron.
Infusion/Guidewire Exchange
Catheter
Cleared Date: 15-MAR-1995

BK870011 Seabrook Medical Systems, Inc.
673 Wilmer Aveune
Cincinnati, OH 45226
Trade Name:ECMO-TEMP
Cleared Date: 14-SEP-1987

BK820005 Separation Science Corporation
169 Avon Street, P.O. Box 643
Stratford, CT 06497
Trade Name:SEPCOR Cell Line Monitor
Cleared Date: 06-JUL-1982

BK880005 Separation Science Corporation
169 Avon Street, P.O. Box 643
Stratford, CT 06497
Trade Name:Blood Bank Saline, Preserved
Cleared Date: 09-JUN-1988

BK050056 Separation Technology, Inc.
1096 Rainier Drive
Altamonte Springs, FL 32714-3855
Trade Name:UltraChek Reference Controls -
Product Code GLK
UltraCrit™ Hematocrit Measurement
Device - Product Code GKF
Cleared Date: 12-DEC-2005

BK960036 Shared Medical Systems
51 Valley Stream Parkway
Malvern, PA 19355
Trade Name:SMS BB Transfusion System
Cleared Date: 12-DEC-1997

BK990018 Shotwell & Carr, Inc.
3535 Firewheel Drive
Suite A
Flower Mound, TX 75028-2628
Trade Name:Hot Shot Fluid Warmer Model 100
Hot Shot Fluid Warmer Model 101
Hot Shot Fluid Warmer Model 102
Hot Shot Fluid Warmer Model 103
Cleared Date: 13-OCT-1999

BK040018 sienna partners
P.O. Box 103
Baldwin, MD 21013
Trade Name:Vacuette EDTA K2 tube; Vacuette
EDTA K3 tube
Cleared Date: 28-JUL-2004

BK040066 sienna partners
P.O. Box 103
Baldwin, MD 21013
Trade Name:Greiner VACUETTE No Additive
Evacuated Blood Collection Tubes
and Serum Clot Activator Blood
Collection Tubes
Cleared Date: 10-SEP-2004

BK090077 Siemens Healthcare Diagnostics Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 28-DEC-2009

BK110007 Siemens Healthcare Diagnostics Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 04-MAR-2011

BK120013 Siemens Healthcare Diagnostics Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 27-MAR-2012

BK960051 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name:PPIS - Version 2.0
Cleared Date: 07-AUG-1998
Cleared Under Bayer Corporation

BK990024 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name:Plasma Procurement Information
System (PPIS) - 3.0
Cleared Date: 03-NOV-1999
Cleared Under Bayer Corporation

BK990037 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name:Plasma Procurement Information
System (PPIS) - Version 4.0
Cleared Date: 17-NOV-1999
Cleared Under Bayer Corporation

BK060015 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name:TRUGENE HIV-1 Genotyping Kit and

OpenGene DNA Sequencing System
Cleared Date: 21-MAR-2006
Cleared Under Bayer HealthCare Diagnostics
Division

- BK070009 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 19-MAR-2007
- BK080036 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 20-OCT-2008
- BK080073 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 15-JAN-2009
- BK850011 Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name:Accugenics (Tray)
Cleared Date: 07-AUG-1985
- BK850012 Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name:Accugenics (HLA Control Cells)
Cleared Date: 07-AUG-1985
- BK080047 SofTov Ltd
32 HaShacham Street
Petach Tikva, Israel 49170
Trade Name:AutoFusion - v3.02
Cleared Date: 05-JUN-2009
- BK960033 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftBank II Version 19.1
Cleared Date: 10-JUL-1998
- BK000040 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftBank II - 21.2
Cleared Date: 20-APR-2001
- BK020006 Soft Computer Consultants Inc.

34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftDonor - 4.1
Cleared Date: 27-FEB-2003

BK020021 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftBank II - 22
Cleared Date: 11-SEP-2002

BK030018 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftBank II - 23
Cleared Date: 17-APR-2003

BK040028 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftBank II with SoftScape - 23
Cleared Date: 07-MAY-2004

BK040048 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name:SoftBank II with Database
Management System Interface (DMSI)
- v23.1
Cleared Date: 23-AUG-2004

BK970032 Sorvall, Inc.
31 Pecks Lane
Newtown, CT 06470
Trade Name:RC12BP
Cleared Date: 05-DEC-1997

BK030064 Stemco Biomedical, Incorporated
2810 Meridian Parkway
Suite 148
Durham, NC 27713
Trade Name:Aldecourt Progenitor Cell
Enumeration Kit
Cleared Date: 31-DEC-2003

BK040075 Stemco Biomedical, Incorporated
2810 Meridian Parkway
Suite 148
Durham, NC 27713
Trade Name:Aldecourt Progenitor Cell
Enumeration Kit
Cleared Date: 06-JAN-2005

BK860030 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name:Stephens Scientific Certified

Blood Bank Saline
Cleared Date: 16-DEC-1986

BK870015 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name:Certified Blood Bank Saline,
Preserved
Cleared Date: 02-NOV-1987

BK870016 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name:Certified Saline, Preserved
Cleared Date: 02-NOV-1987

BK880013 Stericon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name:RCM-10 Pediatric Sized Freezing
Bag
Cleared Date: 09-NOV-1988

BK920022 Stericon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name:MB-30 Empty Plastic Containers
Cleared Date: 03-JUN-1993

BK990002 Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name:Flexilab - 5.2
Cleared Date: 16-AUG-1999

BK990034 Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name:FlexiLab Blood Bank and Blood
Donor System - Version 5.2
Cleared Date: 17-NOV-1999

BK080021 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name:Sunquest Transfusion Manager -
v1.0
Cleared Date: 03-DEC-2008

BK080042 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name:Sunquest Blood Bank Donor - 6.4
Cleared Date: 03-MAR-2009

BK960034 SysTec Computer Associates, Inc.
738 Smithtown Bypass

Smithtown, NY 11787
Trade Name:Lifetec Comm. Blood Center System-
Rev 2.10
Cleared Date: 28-JUL-1998

BK990003 SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name:LifeTec - 2.20
Cleared Date: 30-JUL-1999

BK040026 SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name:LifeTec Donor Verification and
Collection System (DOVAC) - 1.00
Cleared Date: 21-OCT-2004

BK060032 SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name:LifeTec Elite - 1.0
Cleared Date: 15-AUG-2006

BK080067 Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, IL 60060
Trade Name:Sysmex XE-2100D and XS-1000i
Cleared Date: 08-SEP-2009

BK120012 TERUMO Corporation
10810 W. Collins Avenue
Lakewood, CO 80215
Trade Name:Spectra Optia Apheresis System
Cleared Date: 09-JUL-2012

BK120017 TERUMO Corporation
10810 W. Collins Avenue
Lakewood, CO 80215
Trade Name:Trima Accel Automated Blood
Component Collection System
Cleared Date: 31-MAY-2012

BK970012 Tahoe Chemical R & D
2230 Damon Road
Carson City, NV 89701
Trade Name:Nover Trip Scale Alarm
Cleared Date: 14-JUL-1997

BK040062 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name:Quality Donor System 2004 - 2.0
Cleared Date: 18-OCT-2004

BK060031 Talisman Ltd.
421 Church Street NE. Suite F

Vienna, VA 22180
Trade Name:Talisman Phlebotomy System Release
1.0
Cleared Date: 27-JUL-2006

BK070020 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name:Quality Donor System - v2.1
Cleared Date: 16-JUL-2007

BK980021 Talon Medical, Ltd.
18160 Highway 281 N
Suite 108
San Antonio, TX 78232
Trade Name:Cord-X System
Cleared Date: 20-JAN-1999

BK050003 Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name:LIFECODES HLA-A Typing Kit for use
with Luminex 100, LIFECODES HLA-B
Typing Kit for use with Luminex
100, HLA-C Typing Kit for use with
Luminex 100
LIFECODES HLA-DQB Typing Kit for
use with Luminex 100 and
LIFECODES HLA-DRB Typing Kit for
use with Luminex 100
Cleared Date: 18-JUL-2005

BK080050 Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name:LIFECODES HLA Typing Kits (HLA-A,
B, C, DQB, DRB, DRB1) for use with
Luminex
Cleared Date: 13-NOV-2008

BK090018 Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name:LIFECODES Evolution Software,
version 1.0
Cleared Date: 04-JUN-2009

BK820015 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Plasmafex Pooling Bottle
Cleared Date: 12-NOV-1982

BK850017 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Plasmafex Bottles

Cleared Date: 04-NOV-1985

BK860012 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Imugard Leukocyte Filter
Cleared Date: 16-MAY-1990

BK890005 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Stericell Cell Processor
Cleared Date: 10-OCT-1989

BK890017 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Teruflex Transfer Bag
Cleared Date: 18-JUL-1990

BK890032 Terumo Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:Immugard-E- Leukocyte Removal From
Red Blood Cells
Cleared Date: 18-JUL-1990

BK900028 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Terufusion Plasma Transfer Set
Cleared Date: 22-OCT-1990

BK920040 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name:Venject II Holder
Cleared Date: 20-MAY-1993

BK950039 Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name:Teruflex B-600 Terumo Blood Bag
without anticoagulant
Cleared Date: 25-AUG-1995

BK950058 Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name:Terumo Sampling Site Coupler
Cleared Date: 13-NOV-1995

BK860041 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:SCD 312
Cleared Date: 01-JUN-1987

BK970008 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:Terumo Sterile Tubing Welder SC-
201A (TSCD)
Cleared Date: 28-MAY-1998

BK970011 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:Terumo Phlebotomy Needle Cap
Holder
Cleared Date: 19-JUN-1997

BK000045 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:Imugard III-PL
Cleared Date: 28-SEP-2001

BK020033 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:Imugard III-PL Leukocyte reduction
filter
Cleared Date: 22-MAY-2003

BK040082 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:TSCD-II Terumo Sterile Tubing
Welder
Cleared Date: 05-APR-2005

BK070018 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name:TRUCISE Total System
Cleared Date: 22-JAN-2008

BK980002 Teva Medical LTD
482 Hudson Terrace
Englewood Cliffs, NJ 07632
Trade Name:SegMed
Cleared Date: 02-MAR-1998

BK060060 Texas BioGene, Inc.
635 Presidential Drive
Richardson, TX 75081
Trade Name:Morgan HLA SSP ABDR Typing Kit
Cleared Date: 22-MAR-2007

BK080039 Texas BioGene, Inc.
635 Presidential Drive
Richardson, TX 75081
Trade Name:Morgan HLA SSP ABCDRDQ Typing Kit

Cleared Date: 22-APR-2009

BK050058 The Surgical Company International
Terminalweg 19a
Amersfoort, Netherlands 3821 AJ
Trade Name:Fluido Blood and Fluid Warmer
System
Cleared Date: 05-MAY-2006

BK070055 The Surgical Company International
Terminalweg 19a
Amersfoort, Netherlands 3821 AJ
Trade Name:Fluido Air Guard
Fluido Compressor
Fluido IV-Pole
Fluido Pressure Chamber
Cleared Date: 15-JAN-2008

BK950067 Thermal Transfer Technology
681 Main Street
Placerville, CA 95667
Trade Name:Thermal Ware
Cleared Date: 14-FEB-1996

BK960072 Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name:CryoSeal System
Cleared Date: 12-FEB-1999

BK960074 Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name:HemoMatic Blood Collection Monitor
Cleared Date: 03-APR-1997

BK030011 Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name:ThermoGenesis Thawer
Cleared Date: 10-JUN-2003

BK070006 Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name:AXP AutoXpress Platform
Cleared Date: 05-OCT-2007

BK100066 Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name:ThermoGenesis Res-Q60 PRP Device
Cleared Date: 27-MAY-2011

BK900017 Thermopol Inc.
2481 B Delta Ln,
Elk Grove Village, IL 60007
Trade Name:Solid State Portable Refrigerator
Cleared Date: 30-AUG-1990

BK940038 Thomson & Neilsen, Ltd.
1050 Baxter Road
Ottawa, Ontario, Canada, Canada
Trade Name:Blood Irradiator Dosimetry System
TN-ID-50
Cleared Date: 18-OCT-1994

BK850007 Trayser, Inc.
P.O. Box 83
Cabin John, MD 20818
Trade Name:Trayser DR/DQ Typing Tray Kit
Cleared Date: 25-APR-1985

BK070037 Typenex Medical LLC
303 East Wacker Drive
Suite 311
Chicago, IL 60601
Trade Name:TypeSafe Segment Dispenser
Cleared Date: 05-OCT-2007

BK820012 UCLA Tissue Typing Laboratory
1000 Veteran Avenue
Los Angeles, CA 90024
Trade Name:HLA Typing Tray
Cleared Date: 04-MAR-1983

BK970026 Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name:Umbilicup
Cleared Date: 28-JAN-1998

BK970027 Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name:Umbilicup II Cord Blood System
Cleared Date: 06-JAN-1998

BK010043 VEEGEE Scientific
13600 NE 126th Place
Suite A
Kirkland, WA 98034
Trade Name:Atago SP-D2 Refractometer
Cleared Date: 02-JAN-2002

BK870008 Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name:Normal Saline-Buffered
Cleared Date: 31-JUL-1987

BK880004 Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name:Buffered Normal Saline Concentrate
Cleared Date: 11-APR-1988

BK070044 Verax Biomedical Incorporated
377 Plantation St., Biotech 4
Worcester, MA 01605
Trade Name:Platelet PGD Controls
Platelet PGD Test
Cleared Date: 17-SEP-2007

BK090028 Verax Biomedical Incorporated
377 Plantation St., Biotech 4
Worcester, MA 01605
Trade Name:Platelet PGD Test System
Cleared Date: 10-NOV-2009

BK110014 Verax Biomedical Incorporated
377 Plantation St., Biotech 4
Worcester, MA 01605
Trade Name:Platelet PGD Test System
Cleared Date: 08-SEP-2011

BK020005 Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name:Trugene HIV-1 Genotyping Kit and
Open Gene DNA Sequencing System
Cleared Date: 24-APR-2002

BK020042 Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 07-NOV-2002

BK030015 Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name:TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 14-MAR-2003

BK910010 WHITTAKER BIOPRODUCTS, INC.
8830 Biggs Ford Road
Walkersville, MO 21793
Trade Name:ENDOTOXIN CHALLENGE VIALS
Cleared Date: 09-AUG-1991

BK860039 Wako Chemicals, USA, Inc.
12300 Ford Road, Suite 130
Dallas, TX 75234
Trade Name:Toxinometer ET-201
Cleared Date: 10-FEB-1987

BK910005 Whitman Medical Corporation
990 Raritan Road
Clark, NJ 07066
Trade Name:Safe-T-Vue Irreversible
Temperature Indicator
Cleared Date: 12-MAY-1992

BK950059 Wyndgate Technologies
11121 Sun Center Drive
Suite C
Rancho Cordova, CA 95670
Trade Name:Safe Trace
Cleared Date: 14-APR-1997

BK980023 Wyndgate Technologies
11060 White Rock Road
Suite 200
Rancho Cordova, CA 95670
Trade Name:SafeTrace TX, version 1.0
Cleared Date: 29-JAN-1999

BK070010 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name:ElDorado Donor Doc - 1.0.0
Cleared Date: 23-MAY-2007

BK070064 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name:ElDorado Donor - 1.0.0
Cleared Date: 13-FEB-2008

BK090026 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name:Safe Trace Tx
Cleared Date: 03-SEP-2009

BK090033 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name:ElDorodo Donor Doc
Cleared Date: 28-OCT-2009

BK090063 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name:Test Result Interface for ElDorado
Donor
Cleared Date: 20-NOV-2009

BK100002 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name:Component Manufacturing Interface
for ElDorado Donor
Cleared Date: 24-FEB-2010