3T MEDICAL SYSTEMS, LLC. ATTN: TIMOTHY J SIMMONS 6770 PINE WAY DRIVE TROY, MI 48098	510(k) NO: K001245 PHONE NO : 248-879-6968	DEVICE: 3T L. V. CONTROL VALVE SE DECISION MADE: 15-AUG-2001 510(k) STATEMENT
AB ARDENT ATTN: CLYDE E INGERSOLL 54 RIVERVIEW AVE TONAWANDA, NY 14150-5260	510(k) NO: K011801 PHONE NO : 716-693-6591	DEVICE: FUTURA TOPCAP NON GAMMA-2 SE DECISION MADE: 16-AUG-2001 510(k) STATEMENT
ACCELERATED REHAB DESIGNS, INC. ATTN: RANDALL POTTER 32025 INDUSTRIAL PARK DR. PINEHURST, TX 77362	510(k) NO: K012281 PHONE NO : 281-356-1950	DEVICE: TRS-2000 POWER TILT/POWER RECLINE SYSTEM SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACCURAY, INC. ATTN: E. BRUCE FLOYD 570 DEL REY AVE. SUNNYVALE, CA 94085	510(k) NO: K011024 PHONE NO : 408-522-3740	DEVICE: CYBERKNIFE SYSTEM SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. PHENCYCLIDINE TEST DEVICE ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K011730 PHONE NO : 858-535-2030	DEVICE: ACON PCP ONE-STEP PHENCYCLIDINE TEST STRIP, ACON PCP ONE-STEP SE DECISION MADE: 09-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K012215 PHONE NO : 858-535-2030	DEVICE: QUIK-CHECK HOME PREGNANCY TEST SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. ATTN: FRAN WHITE 163 CABOT STREET BEVERLY, MA 01915	510(k) NO: K012252 PHONE NO :	DEVICE: QUIK-CHECK OVULATION PREDICTOR SE DECISION MADE: 24-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ADVANTAGE DIAGNOSTICS CORP. ATTN: JANIS FREESTONE 4 HOLYROOD STREET CHARD, SOMERSET,	510(k) NO: K011962 PHONE NO : 44 146 067925	DEVICE: ADVANTAGE MARIJUANA (THC) AND COCAINE HOME DRUG TEST SE DECISION MADE: 09-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA M MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K011102 PHONE NO : 800-258-1946	DEVICE: ANTERIOR CRUCIATE LIGAMENT (ACL) INSTRUMENT SYSTEM SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

945-0120

LST 105

AESCULAP, INC.
E
ATTN: STEVE REITZLER
13221 MARICOITE PLACE
SAN DIEGO, CA 92130

510(k) NO: K011372
PHONE NO : 619-977-1465

DEVICE: AESCULAP, INC. SAFIL QUICK SYNTHETIC ABSORBABLE SURGICAL SUTUR
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
ATTN: ERICA SETHI
1500 WAUKEGAN RD.
MCGAW PARK, IL 60085

510(k) NO: K011721
PHONE NO : 847-785-3337

DEVICE: ESTEEM STERILE POLYISOPRENE SURGICAL GLOVES
SE DECISION MADE: 14-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALOKA CO., LTD.
ATTN: KELVIN BURROUGHS
10 FAIRFIELD BLVD.
WALLINGFORD, CT 06492

510(k) NO: K012080
PHONE NO : 203-269-5088

DEVICE: SSD-5000 DIAGNOSTIC ULTRASOUND SYSTEM
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALOKA CO., LTD.
ATTN: KELVIN BURROUGHS
10 FAIRFIELD BLVD.
WALLINGFORD, CT 06492

510(k) NO: K012253
PHONE NO : 203-269-5088

DEVICE: SSD-1000 DIAGNOSTIC ULTRASOUND SYSTEM
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN DENT-ALL, INC.
ATTN: VACHAKAN H KHOIE
5140 SAN FERNANDO ROAD
GLENDALE, CA 91204

510(k) NO: K011705
PHONE NO : 818-662-0618

DEVICE: SUPREMCAST
SE DECISION MADE: 03-AUG-2001
510(k) STATEMENT

AMERICAN DENT-ALL, INC.
ATTN: VACHAKAN H KHOIE
5140 SAN FERNANDO ROAD
GLENDALE, CA 91204

510(k) NO: K011706
PHONE NO : 818-662-0618

DEVICE: FLEXICAST PRIME
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

AMERICAN DENTAL TECHNOLOGIES, INC.
ATTN: JOHN VICKERS
5555 BEAR LANE
CORPUS CHRISTI, TX 78405

510(k) NO: K012213
PHONE NO : 361-289-1145

DEVICE: GULLIVER AND CLASSE A
SE DECISION MADE: 13-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: GINGER S GLASER
10700 BREN RD., WEST
MINNETONKA, MN 55343

510(k) NO: K011251
PHONE NO : 952-930-6541

DEVICE: SPARC SLING SYSTEM
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANIMAS CORP.
ATTN: MICHAEL J ANDREWS
590 E. LANCASTER AVENUE
FRAZER, PA 19355

510(k) NO: K012754
PHONE NO : 610-644-8990

DEVICE: EZ SET INFUSION SET
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

APEX DENTAL MATERIALS, INC. ATTN: SCOTT LAMERAND 603 BERKLEY COURT SCHUMBURG, IL 60194	510(k) NO: K010544 PHONE NO : 847-490-1014	DEVICE: VERTEX L/C ORTHODONTIC DIRECT BONDING PASTE SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX DENTAL MATERIALS, INC. ATTN: SCOTT LAMERAND 603 BERKLEY COURT SCHUMBURG, IL 60194	510(k) NO: K010547 PHONE NO : 847-490-1014	DEVICE: VERTEX SEALAND L/C ORTHODONTIC SEALANT SE DECISION MADE: 16-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX MEDICAL CORP. MODEL TS-140600 ATTN: DANIEL LEE 10TH FL., NO. 31, LANE 169, KANG NING ST. HSI CHIH CHEN, TAIPEI HSIEN,	510(k) NO: K002339 PHONE NO : 886 226 954122	DEVICE: AEMS V, EMS-1000, MODEL TS-140500 AND AEMS VI, EMS-1000 PLUS, SE DECISION MADE: 24-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
APPLIED MEDICAL TECHNOLOGY, INC. ATTN: CHRIS ZANTOPULOS 15653 NEO PKWY. CLEVELAND, OH 44128	510(k) NO: K012476 PHONE NO : 216-475-5577	DEVICE: MONARCH, TRANSSHAPING GASTROSTOMY TUBE MODEL 9-2010 SE DECISION MADE: 31-AUG-2001 510(k) STATEMENT
APPRIVA MEDICAL, INC. HETER (WITH DILATOR), MODELS PL-12-12-09, PL-12-12-10 ATTN: MICHAEL KOLBER 777 NORTH PASTORIA AVE. SUNNYVALE, CA 94086	510(k) NO: K012489 PHONE NO : 408-616-5203	DEVICE: MODIFICATION TO: X-SEPT TRANSSEPTAL SHEALTH AND TRANSITION CAT SE DECISION MADE: 30-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: ANN WATERHOUSE 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K011495 PHONE NO : 941-643-5553	DEVICE: ARTHREX BIO-POST AND WASHER SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ASTRA TECH, INC. ATTN: BRUCE R MANNING 96 WEST MAIN STREET NORTHBOROUGH, MA 01532	510(k) NO: K012374 PHONE NO : 508-393-3100	DEVICE: MODIFICATION TO: LOFRIC PLUS SINGLE USE URINARY CATHETER SE DECISION MADE: 23-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ATRICURE, INC. ATTN: MARK L FRIEDMAN 6033 SCHUMACHER PARK DRIVE WEST CHESTER, OHIO, OH 45069	510(k) NO: K011722 PHONE NO : 513-755-4105	DEVICE: ATRICURE BIPOLAR COAGULATION SYSTEM SE DECISION MADE: 30-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ATYS MEDICAL ATTN: CHRISTINE TURLAT 17, PARC D' ARBORA SOUCIEU EN JARREST,	510(k) NO: K012369 PHONE NO : 33 4 78056969	DEVICE: BASIC, MODELS BASIC 1, BASIC 2, AND BASIC 3 SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

AXYA MEDICAL, INC.
ATTN: HOWARD L SCHRAYER
100 CUMMINGS CENTER
SUITE 444C
BEVERLY, MA 01915

510(k) NO: K011912
PHONE NO : 609-924-9510

DEVICE: MODEL 2000 AXYALOOP SELF-TAPPING BONE ANCHOR, MODEL 2000
SE DECISION MADE: 31-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

BASIC DENTAL IMPLANT SYSTEMS, INC.
L IMPLANT SYSTEM
ATTN: DAN BLACKLOCK
3321 COLUMBIA, N.E.
ALBUQUERQUE, NM 87107-2001

510(k) NO: K012299
PHONE NO : 505-881-1376

DEVICE: MODIFICATION TO: STRAIGHT POST AND CORE II FOR THE BASIC DENTA
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAUMER S.A.
ATTN: BRENO CORREA FARAGO JR.
AV. PREF. ANTONIO TAVARES
LEITE NR: 181
MOGI MIRIM, SAO PAULO,

510(k) NO: K011504
PHONE NO : 551 938 063030

DEVICE: BAUMER LOCKING NAIL
SE DECISION MADE: 14-AUG-2001

510(k) STATEMENT

BAYER CORP.
ATTN: WILLIAM J PIGNATO
63 NORTH ST.
MEDFIELD, MA 02052-1688

510(k) NO: K010755
PHONE NO : 508-359-3825

DEVICE: BAYER DIAGNOSTICS ADVIA CENTAUR TOXOPLASMA IGM ASSAY
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECTON DICKINSON & CO.
ATTN: M. WENDY BOSSHARDT
1 BECTON DRIVE
FRANKLIN LAKES, NJ 07417-1880

510(k) NO: K011984
PHONE NO : 201-847-6280

DEVICE: BD VACUTAINER PUSH BUTTON BLOOD COLECTION SET
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BEIJING REAGENT LATEX PRODUCTS
ATTN: WANG YANNAN
NO. 30 SOUTH SANLITUN ROAD,
DONGDAQIAO
CHAOWAI, BEIJING, P.R.,

510(k) NO: K012104
PHONE NO : 86 10 81502573

DEVICE: "SNOW LOTUS" POWDER-FREE LATEX SURGEON'S GLOVES
SE DECISION MADE: 21-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

BEST MANUFACTURING COMPANY
ATTN: DAVID C YOUNG
579 EDISON STREET
MENLO, GA 30731

510(k) NO: K012166
PHONE NO : 706-862-2302

DEVICE: NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE (BROWN)
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES
EL 2, MODELS 641 AND 642
ATTN: MARIA ZEBALLOS
9500 JERONIMO RD.
IRVINE, CA 92618-2017

510(k) NO: K012513

PHONE NO : 949-598-1367

DEVICE: LIQUICHEK LIPIDS CONTROL LEVEL 1, LIQUICHEK LIPIDS CONTROL LEV

SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: CAROL LAUSTER
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K003281
PHONE NO : 219-372-1913

DEVICE: LACTOSORB RAPIDFLAP
SE DECISION MADE: 07-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: MARY L VERSTYNEN
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K010635
PHONE NO : 219-267-6639

DEVICE: INTERLOK / HA COPELAND RESURFACING HEADS
SE DECISION MADE: 20-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: MICHELLE MCKINLEY
P.O. BOX 587
WARSAW, IN 46581

510(k) NO: K012348
PHONE NO : 219-267-6639

DEVICE: MAXIM RPG PS FEMORAL COMPONENT
SE DECISION MADE: 15-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIONOSTICS, INC.
NA GL3
ATTN: KATHY STORRO
2 CRAIG RD.
ACTON, MA 01720

510(k) NO: K012430

PHONE NO : 978-263-3856

DEVICE: MULTI-METER GLUCOSE CALIBRATION VERIFICATION MATERIAL, MODEL R

SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIONOSTICS, INC.
MULTI ANALYTE CONTROL, LEVELS 1,2,3
ATTN: KATHY STORRO
2 CRAIG RD.
ACTON, MA 01720

510(k) NO: K012431

PHONE NO : 978-263-3856

DEVICE: COMBITROL TS MULTI ANALYTE CONTROL, LEVELS 1,2,3, AUTOTROL TS

SE DECISION MADE: 28-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOPRO, INC.
ATTN: PATRICK PRINGLE
17 SEVENTEENTH ST.
PORT HURON, MI 48060

510(k) NO: K011459
PHONE NO : 810-982-7777

DEVICE: WUJIN #3 FEMORAL BONE PLATE
SE DECISION MADE: 07-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOPRO, INC.
ATTN: PATRICK PRINGLE
17 SEVENTEENTH ST.
PORT HURON, MI 48060

510(k) NO: K011460
PHONE NO : 810-982-7777

DEVICE: WUJIN #3 TIBIAL BONE PLATE
SE DECISION MADE: 07-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOPSYBELL S.A.S.
ATTN: LUCIO IMPROTA
131 HIGHWOOD DRIVE
SOUTH GLASTONBURY, CT 06073

510(k) NO: K010735
PHONE NO : 860-633-8807

DEVICE: SPEEDYBELL
SE DECISION MADE: 17-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOSOUND ESAOTE, INC.
ATTN: COLLEEN HITTLE
8000 CASTLEWAY DR.
INDIANAPOLIS, IN 46250

510(k) NO: K012728
PHONE NO : 317-849-1793

DEVICE: E-SCAN MRI SYSTEM
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ATTN: THERESA A MCGOVERN
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760-1537

510(k) NO: K003839
PHONE NO : 508-652-5430

DEVICE: CENTRAL VENOUS CATHETER
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ATTN: JODI LYNN GREENIZEN
ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760

510(k) NO: K011906
PHONE NO : 508-652-5008

DEVICE: BACK-UP MEIER GUIDEWIRE
SE DECISION MADE: 13-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ATTN: NICHOLAS CONDAKES
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760-1537

510(k) NO: K012365
PHONE NO : 508-652-5003

DEVICE: VAXCEL DIALYSIS CATHETER
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC/SCIMED
ATTN: CANDICE BURNS
ONE SCIMED PLACE
MAPLE GROVE, MN 55311-1566

510(k) NO: K012216
PHONE NO : 763-494-2845

DEVICE: NIROYAL BILIARY PREMOUNTED STENT SYSTEM
SE DECISION MADE: 17-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRAINLAB, AG
ATTN: RAINER BIRKENBACH
AMMERTHALSTRASSE 8
HEIMSTETTEN,

510(k) NO: K010968
PHONE NO : 498 999 15680

DEVICE: VECTORVISION CT/FLUORO
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARD GUARD SCIENTIFIC SURVIVAL, LT
ATTN: LEONID TRACHTENBERG
2 PERERIS ST., SCIENCE PARK
REHOVOT,

510(k) NO: K012187
PHONE NO : 972 894 84600

DEVICE: CG-3250 MINIRECEIVER
SE DECISION MADE: 14-AUG-2001
510(k) STATEMENT

CERVILENZ INC
ATTN: JUDY F GORDON
2 DELPHINUS
IRVINE, CA 92612

510(k) NO: K011840
PHONE NO : 949-854-6314

DEVICE: CERVILENZ UTERINE MEASURING SOUND
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

CHASE MEDICAL, INC.
ATTN: DAVE JERNON
1704 ENTERPRISE DR.
ATHENS, TX 75751

510(k) NO: K012248
PHONE NO : 972-783-0644

DEVICE: CHASE CARDIOVASCULAR PATCH
SE DECISION MADE: 10-AUG-2001
510(k) STATEMENT

CHEMBIO DIAGNOSTIC SYSTEMS, INC.
ATTN: FRAN WHITE
163 CABOT STREET
BEVERLY,, MA 01915

510(k) NO: K011550
PHONE NO : 987-927-3808

DEVICE: HCG STAT PAK ULTRA-FAST
SE DECISION MADE: 14-AUG-2001
510(k) STATEMENT

CHEMBIO DIAGNOSTIC SYSTEMS, INC.
ATTN: FRAN WHITE
163 CABOT STREET
BEVERLY,, MA 01915

510(k) NO: K011551
PHONE NO : 978-927-3808

DEVICE: SURE CHECK PREGNANCY TEST
SE DECISION MADE: 14-AUG-2001
510(k) STATEMENT

CHRONIMED, INC.
UICKTEK BLOOD GLUCOSE STRIPS, QUICKTEK CONTROL SOLUTION
ATTN: BRUCE A MACFARLANE
6214 BURY DR.
EDEN PRAIRIE, MN 55346

510(k) NO: K010039
PHONE NO : 612-974-4088

DEVICE: QUICKTEK BLOOD GLUCOSE SYSTEM, QUICKTEK BLOOD GLUCOSE METER, Q

SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

CLAY-PARK LABS, INC. ATTN: GARY L YINGLING 1800 MASSACHUSETTS AVE., N.W. WASHINGTON, DC 20036	510(k) NO: K012203 PHONE NO : 202-778-9124	DEVICE: CLAY-PARK LABS, INC. - LUBRICATING JELLY SE DECISION MADE: 27-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CLINICAL CONTROLS DIVISION ATTN: JAMES F GODFREY 12038 CENTRALIA AVE. UNIT C HAWAIIAN GARDENS, CA 90716	510(k) NO: K012855 PHONE NO : 562-809-3389	DEVICE: LIQUISPX LIQUID LIPID CONTROL SE DECISION MADE: 30-AUG-2001 510(k) STATEMENT
COALESCENT SURGICAL ATTN: MICHAEL A DANIEL 559 EAST WEDDELL DR. SUNNYVALE, CA 94089	510(k) NO: K012317 PHONE NO : 415-407-0223	DEVICE: COALESCENT SURGICAL U-CLIP SE DECISION MADE: 31-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
COLLAGEN MATRIX, INC. ATTN: SHU-TUNG LI 509 COMMERCE STREET FRANKLIN LAKES,, NJ 07417	510(k) NO: K011695 PHONE NO : 201-405-1477	DEVICE: COLLAGEN DENTAL MEMBRANE SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: LISA HOPKINS 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K010242 PHONE NO : 812-339-0489	DEVICE: COOK ZILVER BILIARY STENT SE DECISION MADE: 13-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: CHARLES J RYAN 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K010411 PHONE NO : 908-412-7446	DEVICE: PALMAZ GENESIS TRANSHEPATIC BILLARY STENT AND DELIVERY SYSTEM SE DECISION MADE: 27-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: CHUCK RYAN 14201 N.W. 60TH AVE. MIAMI LAKES, FL 33014	510(k) NO: K012087 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS EUROPA N.V. 8 DELIVERY SYSTEM ATTN: CHUCK RYAN 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K012056 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT ON SLALOM .01 SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS, A JOHNSON & JOHNSON CO. ATTN: CHARLES J RYAN 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K012090 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

CORGENIX, INC. UANTITATIVE TEST KIT ATTN: NANCI DEXTER 12061 TEJON ST. WESTMINSTER, CO 80234	510(k) NO: K012567 PHONE NO : 303-457-4345	DEVICE: MODIFICATION TO: REAADS ANTI-PHOSPHATIDYLSERINE IGG/IGM SEMI-Q SE DECISION MADE: 23-AUG-2001 510(k) STATEMENT
CRITICARE SYSTEMS, INC. ATTN: ALEX KAPLAN 20925 CROSSROADS CIRCLE WAUKESHA, WI 53186	510(k) NO: K012059 PHONE NO : 262-798-8282	DEVICE: 8100/8500 VITAL SIGNS MONITOR SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CRYOMEDICAL SCIENCES, INC. ATTN: E.J. SMITH PO BOX 4341 CROFTON, MD 21114	510(k) NO: K011073 PHONE NO : 410-451-0639	DEVICE: CRYOPLAN SYSTEM SE DECISION MADE: 22-AUG-2001 510(k) STATEMENT
CYPRESS MEDICAL PRODUCTS, LTD. ATTN: ANTONIO L GIACCIO 1202 SOUTH ROUTE 31 MCHENRY, IL 60050	510(k) NO: K012282 PHONE NO : 815-385-0100	DEVICE: STERILE POWDER FREE SYNTHETIC VINYL PATIENT EXAM GLOVE SE DECISION MADE: 06-AUG-2001 510(k) STATEMENT
DADE BEHRING, , INC. ATTN: CYNTHIA VAN DUKER 2040 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K010418 PHONE NO : 916-374-3105	DEVICE: DRIED GRAM-NEGATIVE AND GRAM-POSITIVE MIC/COMBO PANELS SE DECISION MADE: 22-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: REBECCA S AYASH P.O. BOX 6101 NEWARK,, DE 19714	510(k) NO: K011665 PHONE NO : 302-631-6276	DEVICE: BCT SYSTEM SE DECISION MADE: 09-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
DAVOL, INC., SUB. C.R. BARD, INC. ATTN: LUCINDA L FOX 100 SOCKANOSSETT CROSSROAD CRANSTON, RI 02920	510(k) NO: K011069 PHONE NO : 401-463-7000	DEVICE: AQUASENS FLUID MONITORING SYSTEM SE DECISION MADE: 16-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
DEGUSSA - NEY DENTAL, INC. ATTN: THOMAS C CAMERON 65 WEST DUDLEY TOWN RD. BLOOMFIELD, CT 06002	510(k) NO: K011333 PHONE NO : 800-243-1942	DEVICE: CERCON CERAM SE DECISION MADE: 20-AUG-2001 510(k) STATEMENT
DENPLUS, INC. ATTN: SHUOJIA DONG 1221 LABADIE, SUITE 205 LONGUEUIL, QUEBEC,	510(k) NO: K011762 PHONE NO : 450 646 1330	DEVICE: HI-WAVE; POUR-PLUS SE DECISION MADE: 23-AUG-2001 510(k) STATEMENT

DIAGNOSTIC PRODUCTS CORP.
00 TESTS)
ATTN: EDWARD M LEVINE
5700 WEST 96TH ST.
LOS ANGELES, CA 90045

510(k) NO: K012311
PHONE NO : 310-645-8200

DEVICE: IMMULITE 2000 GENTAMICIN, MODELS L2KGE2 (200 TESTS), L2KGE6 (6

SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DIAGNOSTIC PRODUCTS CORP.
00 TESTS)
ATTN: EDWARD M LEVINE
5700 WEST 96TH ST.
LOS ANGELES, CA 90045

510(k) NO: K012312
PHONE NO : 310-645-8200

DEVICE: IMMULITE 2000 TOBRAMYCN, MODELS L2KTC2 (2002 TESTS), L2KTC6 (6

SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DIAMEDIX CORP.
ATTN: LYNNE STIRLING
2140 NORTH MIAMI AVE.
MIAMI, FL 33127

510(k) NO: K012053
PHONE NO : 305-324-2354

DEVICE: DIAMEDIX IS-ANTI-CARDIOLIPIN SCREEN TEST SYSTEM
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DIATEK, INC.
400PC, CC2800PC, CC3200PC(32 CM),
ATTN: TODD CASSIDY
101 N. CHESTNUTS ST.
WINSTON-SALEM, NC 27101

510(k) NO: K010399
CC3200PC(36 CM)
PHONE NO : 336-725-9711

DEVICE: DIATEK CANNON-CATH #CC2400, CC2800, CC3200, CC3600,CC5500. CC2

SE DECISION MADE: 14-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DMG USA, INC.
ATTN: PAMELA PAPINEAU
5 WHITCOMB AVENUE
AYER, MA 01432

510(k) NO: K012307
PHONE NO : 978-772-3552

DEVICE: LUXACORE/LUXACORE DUAL
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DMG USA, INC.
ATTN: PAMELA PAPINEAU
414 SOUTH STATE STREET
DOVER, DE 19901

510(k) NO: K012316
PHONE NO : 978-772-3552

DEVICE: PERMACEM / PERMACEM DUAL
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DNI NEVADA, INC.
ATTN: KRISTINE BOGGS
2000 ARROWHEAD DR.
CARSON CITY, NV 89706-0403

510(k) NO: K011729
PHONE NO : 775-883-3400

DEVICE: SIGMA PACE EXTERNAL PACEMAKER ANALYZER MODEL #1000
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DORNIER
"DOLI S-XP")
ATTN: SUZANNEW COURTNEY
1155 ROBERTS BOULEVARD
KENNESAW, GA 30144

510(k) NO: K011873

PHONE NO : 770-514-6204

DEVICE: DORNIER LITHOTRIPTER S("DOLI S") & DORNIER LITHOTRIPTER S-XP (

SE DECISION MADE: 31-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DR. IHDE DENTAL AG SWITZERLAND
IMPLANT SYSTEM, LONG NECK, MODEL
ATTN: MOURAD BARAKET
BATTERY PLACE 70, RIVERWATCH
SUITE 406
NEW YORK, NY 10280

510(k) NO: K991822
STI RT LN LENGTH
PHONE NO : 212-217-2222

DEVICE: ALLFIT IMPLANT SYSTEM, SHORT NECK, MODEL STI RT LENGTH, ALLFIT

SE DECISION MADE: 15-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

EASTMAN KODAK COMPANY ATTN: ANNE ZAVERINIK 343 STATE ST. ROCHESTER, NY 14650	510(k) NO: K012155 PHONE NO : 716-724-4795	DEVICE: KODAK RADIATION ONCOLOGY SOFTWARE/ FOR ACR SYSTEMS SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: JON CAPAROTTA 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K011386 PHONE NO : 973-299-9300	DEVICE: EBI OSTEOSTIM GRANULES-RESORBABLE BONE GRAFT SUBSTITUTE SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ELECTRO MEDICAL SYSTEMS SA ATTN: SHEILA HEMEON-HEYER 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K012445 PHONE NO : 508-643-0434	DEVICE: EMS SWISS LITHOCLAST MASTER (A.K.A. SWISS LITHOCLAST ULTRA) SE DECISION MADE: 24-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ELEKTA ONCOLOGY SYSTEMS, LTD.) ATTN: PETER STEGAGNO 3155 NORTHWOODS PARKWAY NORCROSS, GA 30071	510(k) NO: K012289 PHONE NO : 770-300-9725	DEVICE: MODIFICATION TO: VIEWGT ELECTRONIC PORTAL IMAGING DEVICE (EPID SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
EMBRYOTECH LABORATORIES, INC. LITY ATTN: ANN D MCGONIGLE 19 SEDGEMEADOW ROAD WAYLAND, MA 01778	510(k) NO: K011679 PHONE NO : 508-358-9114	DEVICE: FERTILMARQ HOME DIAGNOSTIC SCREENING TEST KIT FOR MALE INFERTI SE DECISION MADE: 15-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ENCORE ORTHOPEDICS, INC. ATTN: JOANNA DROEGE 9800 METRIC BLVD. AUSTIN, TX 78758	510(k) NO: K011856 PHONE NO : 512-832-9500	DEVICE: RADIOGRAPHIC MARKERS SE DECISION MADE: 22-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ENDIUS, INC. ATTN: SUSAN FINNERAN 23 WEST BACON ST. PLAINVILLE, MA 02762	510(k) NO: K012488 PHONE NO : 508-643-0983	DEVICE: MODIFICATION TO:ENDIUS BIPOLAR SHEATH SE DECISION MADE: 30-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ETHICON ENDO-SURGERY, INC. ATTN: ELIZABETH MILLER 4545 CREEK RD. CINCINNATI, OH 45242-2839	510(k) NO: K011538 PHONE NO : 513-337-7146	DEVICE: ENDOPATH NON-BLADED SOLID OBTURATOR TROCAR SYSTEM SE DECISION MADE: 09-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ETHICON ENDO-SURGERY, INC. ATTN: KATIE FORDYCE 4545 CREEK RD. CINCINNATI, OH 45242-2839	510(k) NO: K012128 PHONE NO : 513-337-8995	DEVICE: PROTECTIV ACUVANCE IV CATHETER SYSTEM SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

EXACTECH, INC.
ATTN: ROBERT PAXSON
2320 N.W. 66TH CT.
GAINESVILLE, FL 32653

510(k) NO: K012493
PHONE NO : 352-377-1140

DEVICE: ACUMATCH C-SERIES CEMENTED FEMORAL COMPONENT, MODEL SIZE 0
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

EXELINT INTL. CO.
ATTN: ARMAND HAMID
P.O. BOX 3194
CULVER CITY, CA 90231-3194

510(k) NO: K010404
PHONE NO : 310-649-0707

DEVICE: EXCEL I.V. ADMINISTRATION SET
SE DECISION MADE: 30-AUG-2001
510(k) STATEMENT

FASSTECH
ATTN: LEE BRODY
155 MIDDLESEX TURNPIKE
BURLINGTON, MA 01803

510(k) NO: K011983
PHONE NO : 781-229-1500

DEVICE: INSIGHT GENESIS
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

FERRANIA S.P.A.
ATTN: MANNELA PAOLO
57 VIALE DELLA LIBERTA
FERRANIA, SAVONA,

510(k) NO: K012373
PHONE NO : 390 195 221

DEVICE: LIFERAY WL CASSETTE, LIFERAY KW CASSETTE
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

FHC, INC.
ATTN: FREDERICK HAER
9 MAIN STREET
BOWDOINHAM, ME 04008

510(k) NO: K011775
PHONE NO : 207-666-8190

DEVICE: MICRO TARGETING DRIVE SYSTEM
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

FHC, INC.
ATTN: FREDERICK HAER
9 MAIN STREET
BOWDOINHAM, ME 04008

510(k) NO: K011992
PHONE NO : 207-666-8190

DEVICE: FHC MICROTARGETING DRIVE SYSTEM
SE DECISION MADE: 14-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

FIRST SCIENTIFIC LIMITED
ATTN: ADE AKINMADE
7 ROSEHEYWORTH BUSINESS PARK
ABERTILLERY
BLAENAU GWENT, WALES,

510(k) NO: K011521
PHONE NO : 44 149 5320456

DEVICE: ORTHO VLC; ORTHO VLC CAPSULE
SE DECISION MADE: 01-AUG-2001

510(k) STATEMENT

FIXANO SA
ATTN: FRANK FERGUSON
P.O BOX 12038
LA JOLLA, CA 92039-2038

510(k) NO: K012161
PHONE NO : 858-587-1147

DEVICE: FLEX-NAILS
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

FRESENIUS MEDICAL CARE NORTH AMERI
COMBI SETS HEMODIALYSIS BLOOD TUBING SETS
ATTN: ARTHUR EILINSFELD
95 HAYDEN AVE.
LEXINGTON, MA 02420

510(k) NO: K012242
PHONE NO : 781-402-9068

DEVICE: FRESENIUS ARTERIAL BLOODLINE SETS FOR HEMODIALYSIS, FRESENIUS

SE DECISION MADE: 16-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GAMBRO RENAL PRODUCTS ATTN: FEI LAW 1845 MASON AVE. DAYTONA BEACH, FL 32117-5102	510(k) NO: K011368 PHONE NO : 904-274-2811	DEVICE: DRY AC ACID CONCENTRATE MIX FOR BICARBONATE HEMODIALYSIS SE DECISION MADE: 02-AUG-2001 510(k) STATEMENT
GATEWAY ALLOYS, INC. ATTN: JOHN C CONSTANTINE 1702 SCHERER PKWY. ST. CHARLES, MO 63303	510(k) NO: K011659 PHONE NO : 888-357-7291	DEVICE: GPW-SF SE DECISION MADE: 27-AUG-2001 510(k) STATEMENT
GATEWAY ALLOYS, INC. ATTN: JOHN C CONSTANTINE 1702 SCHERER PKWY. ST. CHARLES, MO 63303	510(k) NO: K011661 PHONE NO : 888-357-7291	DEVICE: CONCORD 88 SE DECISION MADE: 27-AUG-2001 510(k) STATEMENT
GC AMERICA, INC. ATTN: TERRY L JORITZ 3737 WEST 127TH ST. ALSIP, IL 60803	510(k) NO: K012134 PHONE NO : 708-597-0900	DEVICE: GC E-LIGHT SE DECISION MADE: 07-AUG-2001 510(k) STATEMENT
GE LUNAR CORP. ATTN: JAMES P RASKOB 726 HEARTLAND TRAIL MADISON, WI 53717	510(k) NO: K011917 PHONE NO : 608-826-7425	DEVICE: ADVANCED HIP ASSESSMENT SOFTWARE SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
GE MEDICAL SYSTEMS ATTN: LARRY A KROGER P.O. BOX 414 MILWAUKEE, WI 53201	510(k) NO: K012200 PHONE NO : 262-544-3894	DEVICE: GE SIGNA 1.5T TWINSPEED MAGNETIC RESONANCE SYSTEM SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
GE MEDICAL SYSTEMS, INC. FOR MRI ATTN: LARRY A KROGER P.O. BOX 414 MILWAUKEE, WI 53201	510(k) NO: K011604 PHONE NO : 262-544-3894	DEVICE: PROSTATE SPECTROSCOPY AND IMAGING EXAM (PROSE) SOFTWARE OPTION SE DECISION MADE: 22-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
GE MEDICAL SYSTEMS, INC. ATTN: LARRY KROGER P.O. BOX 414 MILWAUKEE, WI 53201	510(k) NO: K012313 PHONE NO : 262-544-3894	DEVICE: CT COLONOGRAPHY/NAVIGATOR2 SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
GE MEDICAL SYSTEMS, INC. ATTN: JOHN W JAECKLE P.O. BOX 414 MILWAUKEE, WI 53201	510(k) NO: K012385 PHONE NO : 262-785-5323	DEVICE: HISPEED X/I SMART GANTRY OPTION SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

GE MEDICAL SYSTEMS, INC.
ATTN: JODI PARKER
P.O. BOX 414
MILWAUKEE, WI 53201
510(k) NO: K012389
PHONE NO : 262-548-4964
DEVICE: REVOLUTION XR/D DIGITAL RADIOGRAPHIC IMAGING SYSTEM
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GEBAUER CO.
RAL MOISTURIZER MODEL NUMBER 0386-000-25
ATTN: DENISE E SPELLMAN
9410 ST. CATHERINE AVE.
CLEVELAND, OH 44104
510(k) NO: K981693
PHONE NO : 216-271-5252
DEVICE: SALIVART ORAL MOISTURIZER MODEL NUMBER 03866-009-75 SALIVART C
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GELFLEX
ITON SOFT BIFOCAL CONTACT LENS
ATTN: PETER G BRYANT
THREE HUTTON STREET
OSBORNE PARK
PERTH,
510(k) NO: K011072
PHONE NO : 618 944 34944
DEVICE: GELFLEX TRITON HW SOFT BIFOCAL CONTACT LENS AND THE GELFLEX TR
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GENERAL ELECTRIC CO.
ATTN: ALLEN SCHUH
P.O. BOX 414
MILWAUKEE, WI 53201
510(k) NO: K012560
PHONE NO : 414-647-4385
DEVICE: GE LOGIQ A100 MP, MODEL 2272413
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GENZYME CORP.
ATTN: BARBARA PIZZA
ONE KENDALL SQUARE
CAMBRIDGE, MA 02139-1562
510(k) NO: K011843
PHONE NO : 617-252-7953
DEVICE: GENZYME DIRECT-AMYLASE TEST REAGENT
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GIBBONS SURGICAL CORP.
ATTN: LISA CRISSON
1112 JENSEN DRIVE, STE.101
VIRGINIA BEACH, VA 23451
510(k) NO: K012198
PHONE NO : 757-491-7305
DEVICE: GIBBONS STERILE TROCAR KITS
SE DECISION MADE: 09-AUG-2001
510(k) STATEMENT

GLOBAL SHOP, INC.
ATTN: GARY C BAUMAN
1156 EAST RIDGEWOOD AVE.
PO BOX 1211
RIDGEWOOD, NJ 07450
510(k) NO: K012553
PHONE NO : 201-444-7204
DEVICE: GSIBP BLOOD PRESSURE CUFF
SE DECISION MADE: 17-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GULF COAST HYPERBARICS, INC.
ATTN: JAMES W MCCARTHY
4309 GREEN LEAF CIRCLE
PANAMA CITY, FL 32404
510(k) NO: K011565
PHONE NO : 904-769-2545
DEVICE: INFANT OXYGEN TREATMENT HOOD
SE DECISION MADE: 16-AUG-2001
510(k) STATEMENT

HEALTH & LIFE CO., LTD.
ATTN: SUSAN CHEN
6F,NO. 407, CHUNG SHAN RD.
SEC.02, CHUNG HO CITY
TAIPEI HSIEN,
510(k) NO: K012310
PHONE NO : 886 2 32349600
DEVICE: MODIFICATION TO:HL168D BLOOD PRESSURE MONITOR
SE DECISION MADE: 22-AUG-2001
510(k) STATEMENT

HEALTH@FITNESS TECHNOLOGIES, INC.
ATTN: IVAN VRDOLJAK
KARAMANOVA 11
21000 SPLIT,
510(k) NO: K010807
PHONE NO : 385 213 85828
DEVICE: MUSCLE STIMULATOR SA-100
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

HEATSHIELD, INC.
ATTN: WILLIAM A PLOUMIS
110 LOCKWOOD AVE.
SUITE 400
NEW ROCHELLE, NY 10801
510(k) NO: K011666
PHONE NO : 914-235-0590
DEVICE: CHILLIT
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

HEMATRONIX, INC.
ATTN: JAMES S AFRANKO
524 STONE RD.
SUITE A
BENICIA, CA 94510
510(k) NO: K012243
PHONE NO : 707-746-7833
DEVICE: MCC URICHECK ASSAYED LIQUID URINE MULTICONSTITUENT CONTROL
SE DECISION MADE: 20-AUG-2001
510(k) STATEMENT

HERAEUS KULZER, INC.
ATTN: CHERYL V ZIMMERMAN
4315 SOUTH LAFAYETTE BLVD.
SOUTH BEND, IN 46614-2517
510(k) NO: K012341
PHONE NO : 219-299-6662
DEVICE: TRANSLUX ENERGY
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

HITACHI MEDICAL CORP.
00 DIAGNOSTIC ULTRASOUND SCANNER; SP-711 SONOPROBE SYSTEM
ATTN: WALTER WEYBURNE
660 WHITE PLAINS ROAD
TARRYTOWN, NY 10591-5107
510(k) NO: K012239
PHONE NO : 914-524-9711
DEVICE: MODIFICATIONS TO EUB-525 DIAGNOSTIC ULTRASOUND SCANNER; EUB-20
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

HITACHI MEDICAL SYSTEMS AMERICA, I
ATTN: ROBERT H MCCARTHY
1959 SUMMIT COMMERCE PARK
TWINSBURG, OH 44087-2371
510(k) NO: K011320
PHONE NO : 330-425-1313
DEVICE: ETG-100 OPTICAL ENCEPHALOGRAPHY SYSTEM
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

HOLLISTER, INC.
ATTN: JOSEPH S TOKARZ
2000 HOLLISTER DR.
LIBERTYVILLE, IL 60048
510(k) NO: K011519
PHONE NO : 847-680-2849
DEVICE: AMEDA HYGIENIKIT
SE DECISION MADE: 15-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

HORIZONS INTL. CORP.
ATTN: RAFIC SALEH
P.O. BOX 7273
PONCE, PR 00732-7273
510(k) NO: K011667
PHONE NO : 787-842-4000
DEVICE: HORIZONS INTERNATIONAL POLYPECTOMY SNARES
SE DECISION MADE: 16-AUG-2001
510(k) STATEMENT

HOWMEDICA OSTEONICS CORP.
ATTN: KAREN ARIEMMA
59 ROUTE 17
ALLENDALE, NJ 07401-1677
510(k) NO: K012158
PHONE NO : 201-760-8187
DEVICE: MODIFICATION TO: LONG LENGTH GAMMA NAIL
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

HOWMEDICA OSTEONICS CORP.
ATTN: KAREN ARIEMMA
59 ROUTE 17
ALLENDALE, NJ 07401-1677

510(k) NO: K012162
PHONE NO : 201-760-8187

DEVICE: STRYKER PLATING SYSTEM BASIC FRAGMENT SET
SE DECISION MADE: 31-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

I-STAT CORP.
ATTN: PAUL VANDERWERF
104 WINDSOR CENTER DR.
EAST WINDSOR, NJ 08520

510(k) NO: K012478
PHONE NO : 609-469-0242

DEVICE: MODIFICATION TO: I-STAT PORTABLE CLINICAL ANALYZER
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

IMAGE-GUIDED NEUROLOGICS, INC.
ATTN: DAVID M LEE
2290 W. EAU GALLIE BLVD
SUITE 210
MELBOURNE, FL 32935

510(k) NO: K011971
PHONE NO : 321-309-8237

DEVICE: NAVIGUS TRAJECTORY GUIDE BIOPSY KIT, MODELS BK-7000 AND 8000
SE DECISION MADE: 03-AUG-2001

510(k) STATEMENT

IMAGING SERVICES, INC.
ATTN: DEAN JAMES
8210 LANKERSHIM BLVD., #1
NORTH HOLLYWOOD, CA 91605

510(k) NO: K010772
PHONE NO : 800-900-9729

DEVICE: ISI-2500 CCD C-ARM, ISI-2500 PLUS CCD C-ARM
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

IMAGYN SURGICAL
ATTN: JULIE POWELL
8850 M-89
PO BOX 351
RICHLAND, MI 49083

510(k) NO: K011575
PHONE NO : 616-629-5811

DEVICE: 22MM SITESELECT BREAST BIOPSY DEVICE MODEL SSD022
SE DECISION MADE: 17-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

IMPAC MEDICAL SYSTEMS, INC.
ATTN: THOMAS H FARIS
100 WEST EVELYN AVE.
MOUNTAIN VIEW, CA 94041-1464

510(k) NO: K011694
PHONE NO : 650-623-8807

DEVICE: VIEWSTATION
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

IMPLEX CORP.
ELS 4893-XX-YY (ZIMMER), 02-212-05XX1 (IMPLEX)
ATTN: ROBERT A POGGIE
80 COMMERCE DR.
ALLENDALE, NJ 07401-1600

510(k) NO: K012507
PHONE NO : 201-818-1800

DEVICE: THE TRABECULAR METAL TECHNOLOGY ACETABULAR AUGMENT SYSTEM, MOD

SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

INCISIVE, LLC.
ATTN: MICHAEL YESSIK
3095 RICHMOND PARKWAY
SUITE 213
RICHMOND, CA 94806

510(k) NO: K011423
PHONE NO : 510-669-9401

DEVICE: INPULSE DENTAL LASER
SE DECISION MADE: 07-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

INSTITUT STRAUMANN AG
ATTN: LINDA JALBERT
RESERVOIR PLACE
1601 TRAPELO ROAD
WALTHAM, MA 02451

510(k) NO: K011698
PHONE NO : 800-448-8168

DEVICE: STRAUMANN GBR SYSTEM
SE DECISION MADE: 23-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

INSTITUT STRAUMANN SA
ATTN: LINDA JALBERT
1601 TRAPELO ROAD
RESERVOIR PLACE
WALTHAM, MA 02451

510(k) NO: K003552
PHONE NO : 800-448-8168

DEVICE: ITI DENTAL IMPLANT SYSTEM
SE DECISION MADE: 17-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

INTEGRATION DIAGNOSTICS LTD
ATTN: CONSTANCE BUNDY
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) NO: K003714
PHONE NO : 763-574-1976

DEVICE: OSSTELL RESONANCE FREQUENCY ANALYZER
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

INTERPORE CROSS INTL.
ATTN: LYNN M RODARTI
181 TECHNOLOGY DR.
IRVINE, CA 92618-2402

510(k) NO: K010530
PHONE NO : 949-453-3200

DEVICE: GEO STRUCTURE
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

INTERSECT SYSTEMS, INC.
ATTN: MARK E LEGAZ
P.O. BOX 2219
LONGVIEW, WA 98632

510(k) NO: K011972
PHONE NO : 360-577-1062

DEVICE: DIRECT BILIRUBIN REAGENT
SE DECISION MADE: 27-AUG-2001
510(k) STATEMENT

INTRALASE CORP.
ATTN: JUDY F GORDON
18732 SAGINAW
IRVINE, CA 92612

510(k) NO: K002890
PHONE NO : 949-854-6314

DEVICE: INTRALASE 600C LASER KERATOME
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

INTRALUMINAL THERAPEUTICS, INC.
R ADVANCING MECHANISM, MODEL A11AM1
ATTN: PAMELA MISAJON
6354 CORTE DEL ABETO
SUITE A
CARLSBAD, CA 92009

510(k) NO: K012169
PHONE NO : 760-918-1820

DEVICE: ILT SUPPORT CATHETER .014", MODEL C114LW1; ILT SUPPORT CATHETE

SE DECISION MADE: 30-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

INTRATHERAPEUTICS, INC.
ATTN: AMY PETERSON
651 CAMPUS DR.
ST. PAUL, MN 55112-3495

510(k) NO: K011184
PHONE NO : 612-697-2076

DEVICE: INTRASTENT DOUBLESTRUT PARAMOUNT XS BILIARY ENDOPROSTHESIS
SE DECISION MADE: 13-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

INVACARE CORP.
ATTN: RAE ANN FARROW
ONE INVACARE WAY
P.O. BOX 4028
ELYRIA, OH 44036-2125

510(k) NO: K012167
PHONE NO : 440-329-6000

DEVICE: MODEL TOP END TERMINATOR TITANIUM MANUAL WHEELCHAIR
SE DECISION MADE: 01-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

INVACARE CORP.
ATTN: RAE ANN FARROW
ONE INVACARE WAY
PO BOX 4028
ELYRIA, OH 44035

510(k) NO: K012370
PHONE NO : 440-329-6356

DEVICE: SOLARA JR. MANUAL WHEELCHAIR
SE DECISION MADE: 03-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

IOP, INC.
ATTN: JASON MALECKA
3151 AIRWAY AVE., BLDG. I-1
COSTA MESA, CA 92626

510(k) NO: K010852
PHONE NO : 714-549-1185

DEVICE: OSMED TISSUE EXPANDER
SE DECISION MADE: 13-AUG-2001
510(k) STATEMENT

IVOCLAR NORTH AMERICA, INC.
ATTN: ANDERJEET GULATI
175 PINEVIEW DR.
AMHERST, NY 14228

510(k) NO: K011491
PHONE NO : 716-691-0010

DEVICE: HELIOSEAL CLEAR CHROMA
SE DECISION MADE: 16-AUG-2001
510(k) STATEMENT

IVOCLAR NORTH AMERICA, INC.
ATTN: DONNA M HARTNETT
175 PINEVIEW DR.
AMHERST, NY 14228

510(k) NO: K012174
PHONE NO : 716-691-0010

DEVICE: ERIS LAYERING MATERIALS
SE DECISION MADE: 27-AUG-2001
510(k) STATEMENT

J.F. JELENKO & CO., INC.
ATTN: RAPHAEL JUDKINS
99 BUSINESS PARK DR.
ARMONK, NY 10504

510(k) NO: K012303
PHONE NO : 914-273-8600

DEVICE: JEL-20
SE DECISION MADE: 22-AUG-2001
510(k) STATEMENT

JAS DIAGNOSTIC, INC.
ATTN: DAVID JOHNSTON
7220 NW 58TH ST.
MIAMI, FL 33166

510(k) NO: K012038
PHONE NO : 305-418-2320

DEVICE: JAS URIC ACID LIQUID REAGENT
SE DECISION MADE: 21-AUG-2001
510(k) STATEMENT

JENERIC/PENTRON, INC.
ATTN: ANNMARIE TENERO
53 NORTH PLAINS INDUSTRIAL RD.
P.O. BOX 724
WALLINGFORD, CT 06492-0724

510(k) NO: K011748
PHONE NO : 203-265-7397

DEVICE: FIRST FILL R.C.S.
SE DECISION MADE: 03-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

JENERIC/PENTRON, INC.
ATTN: ANNMARIE TENERO
53 NO.PLAINES INDUSTRIAL ROAD
WALLINGFORD, CT 06492-0724

510(k) NO: K012231
PHONE NO : 203-265-7397

DEVICE: AVANTE MICRO CRYSTAL SYSTEM
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

JET THERAPY
ATTN: OWEN B LAMB
12948 NORTH EAGLE MESA PLACE
MARANA, AZ 85653

510(k) NO: K002908
PHONE NO : 520-572-8414

DEVICE: JET THERAPY
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KAMIYA BIOMEDICAL CO.
ATTN: DON TRAN
910 INDUSTRY DR.
SEATTLE, WA 98188-3412

510(k) NO: K012422
PHONE NO : 206-575-8068

DEVICE: K-ASSAY D-DIMER CONTROLS
SE DECISION MADE: 21-AUG-2001
510(k) STATEMENT

KARL STORZ ENDOSCOPY-AMERICA, INC.
ATTN: JAMES A LEE
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600
510(k) NO: K010345
PHONE NO : 310-338-8100
DEVICE: KSEA MANHES TAKE-APART BIPOLAR COAGULATING FORCEPS
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KARL STORZ ENDOSCOPY-AMERICA, INC.
ATTN: JAMES A LEE
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600
510(k) NO: K010785
PHONE NO : 310-410-2769
DEVICE: KSEA DION-GRACIA SET
SE DECISION MADE: 21-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KENCAP LTD.
ATTN: MARTY DELIN
247 MARGARET KING AVENUE
RINGWOOD, NJ 07456
510(k) NO: K011514
PHONE NO : 973-962-4844
DEVICE: INSTRUMENTS FOR ONE TIME USE - DISPOSABLE
SE DECISION MADE: 13-AUG-2001
510(k) STATEMENT

KEYMED (MEDICAL & INDUSTRIAL EQUIP
ATTN: ROGER GRAY
STOCK RD.
SOUTHEND-ON-SEA, ESSEX,
510(k) NO: K011725
PHONE NO : 44 170 2444276
DEVICE: OLYMPUS SUCTION PUMP, MODEL KV-5
SE DECISION MADE: 31-AUG-2001
510(k) STATEMENT

KIS PRODUCTS
ATTN: REUBEN HERTZ
2318 SEA ISLAND DR.
FT. LAUDERDALE, FL 33301
510(k) NO: K984380
PHONE NO : 954-764-0270
DEVICE: DISPO ETCH
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KIS PRODUCTS
ATTN: REUBEN HERTZ
2318 SEA ISLAND DR.
FT. LAUDERDALE, FL 33301
510(k) NO: K993124
PHONE NO : 954-764-4074
DEVICE: DISPODRILL
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KIS PRODUCTS
ATTN: REUBEN HERTZ
2318 SEA ISLAND DR.
FT. LAUDERDALE, FL 33301
510(k) NO: K993182
PHONE NO : 954-764-4074
DEVICE: DISPOPROPHY
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KMI KOLSTER METHODS, INC.
ATTN: ALWIN H KOLSTER
1170 N. GILBERT ST.
ANAHEIM, CA 92801
510(k) NO: K010702
PHONE NO : 714-956-1964
DEVICE: XUB EXTERNAL ULTRASOUND
SE DECISION MADE: 09-AUG-2001
510(k) STATEMENT

LAB-INTERLINK, INC.
ATTN: DEBORAH S KIPP
1011 SOUTH SADDLE CREEK RD.
OMAHA, NE 68106
510(k) NO: K010500
PHONE NO : 402-595-3767
DEVICE: AUTOMATED WORKCELL CONTROL SOFTWARE
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

LATEXX PARTNERS BHD.
ATTN: CHRISTINA SMITH
PO BOX 4341
CROFTON, MD 21114
510(k) NO: K011791
PHONE NO : 410-451-0639
DEVICE: POWDER FREE NITRILE EXAMINATION GLOVES, VIOLET COLOR
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

LATEXX PARTNERS BHD.
AMINATION GLOVES
ATTN: CHRISTINA SMITH
PO BOX 4341
CROFTON, MD 21114
510(k) NO: K011792
PHONE NO : 410-451-0639
DEVICE: NON-CHLORINATED, POLYMER COATED POWDER-FREE NITRILE PATIENT EX
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

LIGHTMED CORP.
ATTN: GARY LEE
NO.1-1, LANE1,PAO-AN ST. SEC.3
SHULIN CITY,
510(k) NO: K010372
PHONE NO : 886 226 881726
DEVICE: LIGHTLAS 532 PHOTOCOAGULATOR
SE DECISION MADE: 22-AUG-2001
510(k) STATEMENT

LOCKETT MEDICAL CORP.
ATTN: WILLIAM LOCKETT III
THREE RICHMOND SQUARE
PROVIDENCE, RI 02906
510(k) NO: K011176
PHONE NO : 401-421-6599
DEVICE: REUSABLE GLASS SYRINGES
SE DECISION MADE: 10-AUG-2001
510(k) STATEMENT

LUMENIS
NGTH (HO:YAG/ND:YAG) SURGICAL LASERS AND DELIVERY DEVICES
ATTN: LISA MCGRATH
2400 CONDENSA STREET
SANTA CLARA, CA 95051
510(k) NO: K011703
PHONE NO : 408-764-3604
DEVICE: LUMENIS VERSAPULSE POWERSUITE HOLMIUM (HO:YAG) AND DUAL WAVELE
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MACROPORE, INC.
ATTN: KENNETH K KLEINHENZ
6740 TOP GUN ST.
SAN DIEGO, CA 92121
510(k) NO: K011715
PHONE NO : 858-458-0900
DEVICE: MACROPORE IB RESORBABLE PLUG
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MAICO DIAGNOSTIC GMBH
ATTN: DANIEL E EGGAN
9675 WEST 76TH STREET
EDEN PRAIRIE, MN 55344
510(k) NO: K011746
PHONE NO : 952-941-4200
DEVICE: MB 11
SE DECISION MADE: 24-AUG-2001
510(k) STATEMENT

MAINE STANDARDS CO.

ATTN: CHRISTINE BEACH
765 ROOSEVELT TRAIL
WINDHAM, ME 04062-5365
510(k) NO: K012117
PHONE NO : 207-892-1300
DEVICE: VALIDATE CHEM 1 CALIBRATION VERIFICATION TEST SET, MODEL 10001
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MAINE STANDARDS CO.

ATTN: CHRISTINE BEACH
765 ROOSEVELT TRAIL
WINDHAM, ME 04062-5365
510(k) NO: K012118
PHONE NO : 207-892-1300
DEVICE: VALIDATE CHEM 2 CALIBRATION VERIFICATION TEST SET, MODEL 10002
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MAINE STANDARDS CO.

ATTN: CHRISTINE BEACH
765 ROOSEVELT TRAIL
WINDHAM, ME 04062-5365
510(k) NO: K012119
PHONE NO : 207-892-1300
DEVICE: VALIDATE CHEM 3 CALIBRATION VERIFICATION TEST SET, MODEL 10003
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MAINE STANDARDS CO.	510(k) NO: K012120	DEVICE: VALIDATE CHEM 4 CALIBRATION VERIFICATION TEST SET, MODEL 10004
ATTN: CHRISTINE V BEACH 765 ROOSEVELT TRAIL WINDHAM, ME 04062-5365	PHONE NO : 207-892-1300	SE DECISION MADE: 20-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MAINE STANDARDS CO.	510(k) NO: K012122	DEVICE: VALIDATE CHEM 5 CALIBRATION VERIFICATION TEST SET, MODEL 10005
ATTN: CHRISTINE V BEACH 765 ROOSEVELT TRAIL WINDHAM, ME 04062-5365	PHONE NO : 207-892-1300	SE DECISION MADE: 20-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MATERNUS, INC. ATTN: RONALD B HICKS P.O. BOX 782089 SAN ANTONIO, TX 78278	510(k) NO: K011621 PHONE NO : 210-479-4001	DEVICE: KOALA CLAMP, KOALA CLAMP AND CUTTER SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MAVIDON MEDICAL PRODUCTS ATTN: TIM CARROLL 2105 7TH AVE. NO. LAKE WORTH, FL 33461	510(k) NO: K003924 PHONE NO : 800-654-0385	DEVICE: MAVIDON MEDICAL ELECTRODE JELLY SE DECISION MADE: 24-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MAXXIM MEDICAL ATTN: GAIL DOHERTY 1445 FLAT CREEK ROAD ATHENS, TX 75751	510(k) NO: K011905 PHONE NO : 903-675-9321	DEVICE: SNIPER ELITE MODEL-OR-E3872XX SERIES SE DECISION MADE: 28-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL ADVANCES, INC. ATTN: MICHAEL J LEIGH 10437 INNOVATION DR. MILWAUKEE, WI 53226	510(k) NO: K011608 PHONE NO : 414-258-3808	DEVICE: MODEL 235GE-64; MULTI PURPOSE FLEX ARRAY COIL SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL SOLUTIONS, INC. ATTN: BRUCE HEYMANN 3901 CENTERVIEW DR., SUITE W CHANTILLY, VA 20151	510(k) NO: K012276 PHONE NO : 703-736-1639	DEVICE: TEMP 3 SE DECISION MADE: 20-AUG-2001 510(k) STATEMENT
MEDICON, E.G. ATTN: JOACHIM SCHMID GAENSAECKER 15 TUTTLINGEN,	510(k) NO: K010908 PHONE NO : 49 746 220090	DEVICE: MEDICON TITANIUM YASARGIL ANEURYSM CLIPS SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDICON, E.G. ATTN: JOACHIM SCHMID GAENSAECKER 15 TUTTLINGEN,	510(k) NO: K010910 PHONE NO : 49 746 220090	DEVICE: MEDICON YASARGIL CLIP APPLYING FORCEPS SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

MEDISIM LTD.
ATTN: SHOSHANA FRIEDMAN
117 AHUZAH STREET
RA'ANANNA,

510(k) NO: K012217
PHONE NO : 972 977 18130

DEVICE: M5T INSTANT FEVER THERMOMETER
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDRAD, INC.
ATTN: LORRAINE R FREDES
ONE MEDRAD DR.
INDIANOLA, PA 15051

510(k) NO: K011991
PHONE NO : 800-633-7231

DEVICE: MODIFICATION TO MEDRAD SPECTRIS MR INJECTOR
SE DECISION MADE: 21-AUG-2001
510(k) STATEMENT

MEDTECH SYSTEMS, INC.
ATTN: GARY MILLER
4825 OLSON MEMORIAL HIGHWAY,
SUITE 103
GOLDEN VALLEY, MN 55422

510(k) NO: K001853
PHONE NO : 763-417-0598

DEVICE: SYRINGE MANAGEMENT SYSTEM, MODEL SMS-1
SE DECISION MADE: 22-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC AVE, INC.
ATTN: JOHN RIOLO
2170 NORTHPOINT PARKWAY
SANTA ROSA, CA 95407

510(k) NO: K011817
PHONE NO : 707-525-0111

DEVICE: BRIDGE FX
SE DECISION MADE: 22-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC FUNCTIONAL DIAGNOSTICS A510(k) NO: K002992
431,9013S0441,9013S0451,9013S0461,1013S0421,103S0431
ATTN: TOVE KJAER
16-18 TONSBAKKEN
SKOVLUNDE,

PHONE NO : 454 457 9000

DEVICE: DISPOSABLE HYPODERMIC NEEDLE ELECTRODE, MODEL 9013S0421,9013S0

SE DECISION MADE: 15-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC FUNCTIONAL DIAGNOSTICS A510(k) NO: K011472
8 ESOPHAGEAL MANOMETRY APPLICATION, POLYGRAF ID
ATTN: TOVE KJAER
16-18 TONSBAKKEN
SKOVLUNDE,

PHONE NO : 454 457 9000

DEVICE: POLYGRAM 98 ANORECTAL FUNCTION TESTING APPLICATION, POLYGRAM 9

SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC PHYSIO-CONTROL CORP.
ATTN: SHERRI L POCOCK
11811 WILLOWS RD., N.E.
REDMOND, WA 98073

510(k) NO: K010918
PHONE NO : 425-867-4332

DEVICE: LIFEPAK 12 DEFIBRILLATOR/MONITOR SYSTEM
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK, INC.
ATTN: RICHARD W TREHARNE
1800 PYRAMID PL.
MEMPHIS, TN 38132

510(k) NO: K012255
PHONE NO : 901-396-3133

DEVICE: MEDTRONIC SOFAMOR DANEK CEMENT RESTRICTOR
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK, USA
ATTN: RICHARD TREHARNE
1800 PYRAMID PLACE
MEMPHIS, TN 38132

510(k) NO: K011443
PHONE NO : 901-396-3133

DEVICE: THREADED CEMENT RESTRICTOR (CR) TITANIUM
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC, INC. ATTN: PAM SCHAUB 800 53RD AVENUE, N.E. COLUMBIA HEIGHTS, MN 55421-3576	510(k) NO: K010300 PHONE NO : 763-514-7277	DEVICE: MEDTRONIC MODEL 7495LZ LOW IMPEDANCE EXTENSION SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: KAREN REIDT 7000 CENTRAL AVE. N.E. MINNEAPOLIS, MN 55432-3576	510(k) NO: K012083 PHONE NO : 763-514-3914	DEVICE: ATTAIN ACCESS 6218 LEFT-HEART DELIVERY SYSTEM, MODEL 6218 SE DECISION MADE: 28-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: KAREN REIDT 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576	510(k) NO: K012130 PHONE NO : 763-514-3914	DEVICE: ATTAIN LDS 6216 LEFT-HEART DELIVERY SYSTEM SE DECISION MADE: 28-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: KAREN REIDT 7000 CENTRAL AVENUE N.E. MINNEAPOLIS, MN 55432-3576	510(k) NO: K012225 PHONE NO : 763-514-3914	DEVICE: ATTAIN 6215 VENOGRAM BALLOON CATHETER SE DECISION MADE: 28-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: TINA BENOIT 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576	510(k) NO: K012452 PHONE NO : 763-514-4112	DEVICE: MODEL 6500 UNIPOLAR TEMORARY MYOCARDIAL PACING LEAD SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: TINA BENOIT 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576	510(k) NO: K012454 PHONE NO : 763-514-4112	DEVICE: MODEL 6491 UNIPOLAR PEDIATRIC TEMPORARY PACING LEAD SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: TINA BENOIT 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576	510(k) NO: K012458 PHONE NO : 763-514-4112	DEVICE: MODEL 6492 UNIPOLAR TEMPORARY ATRIAL PACING LEAD SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: TINA BENOIT 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576	510(k) NO: K012459 PHONE NO : 763-514-4112	DEVICE: MODEL 6494 UNIPOLAR TEMPORARY MYOCARDIAL PACING WIRE SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: TINA BENOIT 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576	510(k) NO: K012460 PHONE NO : 763-514-4112	DEVICE: MODEL 6495 BIPOLAR TEMPORARY MYOCARDIAL PACING LEAD SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. ATTN: MARIE HOLM 7611 NORTHLAND DRIVE MINNEAPOLIS, MN 55428	510(k) NO: K012538 PHONE NO : 763-391-9183	DEVICE: TUBING AND CONNECTORS WITH TRILLIUM BIOPASSIVE SURFACE SE DECISION MADE: 23-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

MENNEN MEDICAL LTD.
ATTN: ASHER KASSEL
KIRYAT WEIZMANN
P.O. BOX 102
REHOVOT,
510(k) NO: K011784
PHONE NO : 972 8 9383030
DEVICE: MODIFICATION TO ENVOY PATIENT MONITOR
SE DECISION MADE: 16-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MERIT MEDICAL SYSTEMS, INC.
ATTN: DAN REIGLE
1600 WEST MERIT PKWY.
SOUTH JORDAN, UT 84095
510(k) NO: K011811
PHONE NO : 801-253-1600
DEVICE: MONARCH INFLATION SYRINGE; UNIVERSAL FLUID DISPENSING SYRINGE
SE DECISION MADE: 22-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MERITS HEALTH PRODUCTS., INC.
ATTN: WINSTON ANDERSON
P.O. BOX 150356
CAPE CORAL, FL 33915
510(k) NO: K011513
PHONE NO : 800-963-7487
DEVICE: MP3U, POWER WHEELCHAIR
SE DECISION MADE: 10-AUG-2001
510(k) STATEMENT

MERITS HEALTH PRODUCTS., INC.
ATTN: WINSTON ANDERSON
P.O. BOX 150356
CAPE CORAL, FL 33915
510(k) NO: K011687
PHONE NO : 800-963-7487
DEVICE: MP-3C POWER BASE CHAIR, MODEL MP3C
SE DECISION MADE: 03-AUG-2001
510(k) STATEMENT

MERITS HEALTH PRODUCTS., INC.
ATTN: WINSTON ANDERSON
P.O. BOX 150356
CAPE CORAL, FL 33915
510(k) NO: K011751
PHONE NO : 800-963-7487
DEVICE: TRAVEL EASE ELECTRIC SCOOTER, MODEL PIONEER 3
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

MERITS HEALTH PRODUCTS., INC.
ATTN: WINSTON ANDERSON
P.O. BOX 150356
CAPE CORAL, FL 33915
510(k) NO: K011753
PHONE NO : 800-963-7487
DEVICE: TRAVEL EASE ELECTRIC SCOOTER, MODEL PIONEER 4
SE DECISION MADE: 03-AUG-2001
510(k) STATEMENT

MERITS HEALTH PRODUCTS., INC.
ATTN: LEE LEICHTER
7690 CAMERON CIRCLE
FORT MYERS, FL 33912
510(k) NO: K011844
PHONE NO : 941-786-1118
DEVICE: MERITS HEALTH PRODUCTS OXYGEN CONCENTRATORS
SE DECISION MADE: 28-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MERITS MEDICAL INDUSTRIES CO., LTD
ATTN: WINSTON ANDERSON
P.O.BOX 150356
CAPE CORAL, FL 33915
510(k) NO: K011707
PHONE NO : 800-963-7487
DEVICE: TRAVEL EASE ELECTRIC SCOOTER MODEL # PIONEER 2
SE DECISION MADE: 03-AUG-2001
510(k) STATEMENT

MICK RADIO-NUCLEAR INSTRUMENTS, IN
ATTN: FELIX MICK
521 HOMESTEAD AVENUE
MOUNT VERNON, NY 10550
510(k) NO: K011657
PHONE NO : 914-667-3999
DEVICE: HDR TANDEM/RING APPLICATOR WITH RECTAL RETRACTOR
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MICRO THERAPEUTICS, INC.
ATTN: EBEN GORDON
2 GOODYEAR
IRVINE, CA 92618

510(k) NO: K011535
PHONE NO : 949-837-3700

DEVICE: CADENCE PRECISION INJECTOR, MODEL 103-0304
SE DECISION MADE: 02-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MICRO THERAPEUTICS, INC.
ATTN: EBEN GORDON
2 GOODYEAR
IRVINE, CA 92618

510(k) NO: K011937
PHONE NO : 949-837-3700

DEVICE: TRULINE INFUSION CATHETERS
SE DECISION MADE: 28-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MICROGENICS CORP.
ATTN: SHERRIE RINNE
46360 FREMONT BLVD.
FREMONT, CA 94538

510(k) NO: K012109
PHONE NO : 510-979-5150

DEVICE: DRI ECSTASY URINE CALIBRATORS
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MICROGENICS CORP.
ATTN: SHERRIE RINNE
46360 FREMONT BLVD.
FREMONT, CA 94538

510(k) NO: K012110
PHONE NO : 510-979-5150

DEVICE: DRI ECSTASY ENZYME IMMUNOASSAY
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MICROSTIM, INC.
ATTN: JOEL ROSSEN
7881 N.W. 90TH AVE.
TAMARAC, FL 33321

510(k) NO: K010295
PHONE NO : 954-720-4383

DEVICE: MICROSTIM 100I TENS DEVICE
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MILLENNIUM MAGNETIC IMAGING, INC.
ATTN: DONALD H MARKS
210 LORNA SQUARE, PMB 192
HOOVER, AL 35216

510(k) NO: K011416
PHONE NO : 205-283-1688

DEVICE: MUSCLE IMAGING SYSTEM (MIS)
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

MILLS BIOPHARMACEUTICALS, INC.
ATTN: STANLEY MILLS
120 N.E. 26TH ST.
OKLAHOMA CITY, OK 73105

510(k) NO: K011427
PHONE NO : 405-525-3141

DEVICE: MBI PD-103 SL; MBI PD-103 SH
SE DECISION MADE: 31-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MINOLTA CO., LTD.
ATTN: NANCI DEXTER
458 S. RANDOM ROAD
BAILEY, CO 80421

510(k) NO: K010413
PHONE NO : 303-838-8619

DEVICE: MINOLTA PULSOX-3SI, PULSOX-3IA, PULSOX-3LI
SE DECISION MADE: 02-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

MRI DEVICES CORP.
ATTN: THOMAS SCHUBERT
1515 PARAMOUNT DR. SUITE A
WAUKESHA, WI 53186

510(k) NO: K012353
PHONE NO : 262-524-1402

DEVICE: HNC-127 NEUROVASCULAR ARRAY COIL
SE DECISION MADE: 14-AUG-2001
510(k) STATEMENT

NEURO VASX, INC.
ATTN: JACK SLOVICK
7351 KIRKWOOD LANE, SUITE 112
MAPLE GROVE, MN 55369

510(k) NO: K011646
PHONE NO : 763-315-0013

DEVICE: NEUROEDGE INFUSION CATHETER
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NEUROTRON MEDICAL, INC.
ATTN: WHITT ATHEY
12300 TWINBROOK PARKWAY
SUITE 230
ROCKVILLE, MD 20852

510(k) NO: K012069
PHONE NO : 301-770-9590

DEVICE: MODIFICATION TO:BREVIO NERVE CONDUCTION TEST INSTRUMENT
SE DECISION MADE: 01-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

NEUROVISION, INC.
ATTN: RICHARD E LIPPMAN
12300 TWINBROOK PARKWAY
SUITE 230
ROCKVILLE, MD 20852

510(k) NO: K012530
PHONE NO : 301-770-9590

DEVICE: AA-1 SYSTEM
SE DECISION MADE: 31-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

NEW DEAL, S.A.
ATTN: NORMAN F ESTRIN
9109 COPENHAVER DRIVE
POTOMAC, MD 20854

510(k) NO: K011946
PHONE NO : 301-279-2899

DEVICE: THE SPIN SNAP-OFF SCREW
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NEWDEAL S.A.
ATTN: NORMAN F ESTRIN
9109 COPENHAVER DRIVE
POTOMAC, MD 20854

510(k) NO: K011716
PHONE NO : 301-279-2899

DEVICE: THE UNI-CLIP STAPLE
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NEWWAVE MEDICAL LLC.
ATTN: ROBERT ARMSTRONG
620 HAGGARD ST. STE 614
PLANO, TX 75074-5530

510(k) NO: K003631
PHONE NO : 214-516-8383

DEVICE: SMARTWAVE IF 2000
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NIDACON INTERNATIONAL AB
ATTN: DANIEL KAMM
P.O. BOX 7007
DEERFIELD, IL 60015

510(k) NO: K011607
PHONE NO : 847-374-1727

DEVICE: SPERMCATCH
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NIDACON INTERNATIONAL AB
ATTN: DANIEL KAMM
P.O. BOX 7007
DEERFIELD, IL 60015

510(k) NO: K012123
PHONE NO : 847-374-1727

DEVICE: NIDOIL
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NIKO MEDICAL PRODUCTS
0554,40555,440556,40610,40613,40625,40801
ATTN: RICHARD A HAMER
6401 MEADOWS WEST
FORT WORTH, TX 76132

510(k) NO: K003804
PHONE NO : 817-294-3644

DEVICE: SENSI-PREMA NEONATAL ECG ELECTRODES, 40612,40614,40626,40550,4

SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NISHIMOTO SANGYO CO., LTD.
ATTN: GARY J ALLSEBROOK
16303 PANORAMIC WAY
SAN LEANDRO, CA 94578-1116

510(k) NO: K011949
PHONE NO : 510-276-2648

DEVICE: ELK LASER IMAGER, MODEL EL-DRY 4000
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NON-INVASIVE MONITORING SYSTEMS, I510(k) NO: K012020
DEVICE: RESPIEVENTS SOFTWARE IS EVENT DATA PROCESSING SOFWARE FOR A PC

ATTN: ALLAN F BRACK
1840 WEST AVE.
MIAMI BEACH, FL 33139
PHONE NO : 305-534-3694
SE DECISION MADE: 21-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NORTHGATE TECHNOLOGIES, INC.
-05
ATTN: CASEY KUREK
600 CHURCH RD.
ELGIN, IL 60123
510(k) NO: K011928
PHONE NO : 847-608-8900
DEVICE: HYDROTOWER ARTHROSCOPIC ADMINISTRATION TUBING SET, MODEL 7-460
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

NOVA BIOMEDICAL CORP.
ATTN: PAUL W MACDONALD
200 PROSPECT ST.
WALTHAM, MA 02454-9141
510(k) NO: K012058
PHONE NO : 781-894-0800
DEVICE: STAT PROFILE PHOX PLUS L ANALYZER
SE DECISION MADE: 20-AUG-2001
510(k) STATEMENT

OCULAR INSTRUMENTS, INC.
ATTN: RAYMOND GRAHAM
2255 116TH AVE., N.E.
BELLEVUE, WA 98004-3039
510(k) NO: K012096
PHONE NO : 425-455-5200
DEVICE: DISPOSABLE VITRECTOMY LENS
SE DECISION MADE: 24-AUG-2001
510(k) STATEMENT

OLYMPUS AMERICA, INC.
ULTRASONIC GASTROVIDEOSCOPE OLYMPUS GF TYPE UM 160,
ATTN: LAURA STORMS-TYLER
TWO CORPORATE CENTER DR.
MELVILLE, NY 11747-3157
510(k) NO: K011886
PHONE NO : 631-844-5688
DEVICE: OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CTR, EUS EXERA
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

OLYMPUS OPTICAL CO., LTD.
1
ATTN: LAURA STORMS-TYLER
TWO CORPORATE CENTER DRIVE
MELVILLE, NY 11747-3157
510(k) NO: K011484
PHONE NO : 631-844-5688
DEVICE: OLYMPUS INJECTOR NM-4-1, NM-5-1, NM-6-1, NM-7-1, NM-8-1, NM-9-
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

OPUSDENT LTD.
ATTN: SHOSHANA FRIEDMAN
117 AHUZAH ST.
RA'ANANNA,
510(k) NO: K011769
PHONE NO : 972 9 7718150
DEVICE: OPUS 10 (WITH TOOTH WHITENING APPLICATION), MODEL 2ND
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORATEC INTERVENTIONS, INC.
ATTN: LARAINE PANGELINA
3700 HAVEN CT.
MENLO PARK, CA 94025
510(k) NO: K003198
PHONE NO : 650-687-2621
DEVICE: VULCAN TAC PROBES, MODEL 911XXX
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORGANOGENESIS, INC.
ATTN: PATRICK R BILBO
150 DAN RD.
CANTON, MA 02021
510(k) NO: K011025
PHONE NO : 781-401-1155
DEVICE: FORTAFLEX SURGICAL MESH
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORIDION MEDICAL 1987 LTD.
ATTN: SANFORD BROWN
7 HAMARPE ST. P.O. BOX 45025
HAR HOTZVIM INDUSTRIAL PARK
JERUSALEM,

510(k) NO: K012391
PHONE NO : 972 589 9115

DEVICE: MAC-LINE CO2 NASAL CANNULA SAMPLE LINE
SE DECISION MADE: 15-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

ORIDION MEDICAL 1987 LTD.
ATTN: SANFORD BROWN
7 HAMARPE ST. P.O. BOX 45025
HAR HOTZVIM INDUSTRIAL PARK
JERUSALEM,

510(k) NO: K012394
PHONE NO : 972 258 99115

DEVICE: ORIDION MAC-LINE ORAL NASAL CANNULA SAMPLE LINE
SE DECISION MADE: 15-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

ORIDION MEDICAL 1987 LTD.
ATTN: SANFORD BROWN
7 HAMARPE ST. P.O. BOX 45025
HAR HOTZVIM INDUSTRIAL PARK
JERUSALEM,

510(k) NO: K012395
PHONE NO : 972 258 99115

DEVICE: MAC-LINE 02/CO2 NASAL CANNULA SAMPLE LINE
SE DECISION MADE: 15-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

ORTHO DEVELOPMENT CORP.
ATTN: CAROL FREASIER
106 WEST 12200 SOUTH
DRAPER, UT 84020

510(k) NO: K012129
PHONE NO : 801-553-9991

DEVICE: ORTHO DEVELOPMENT ORION-I EMF SYSTEM
SE DECISION MADE: 22-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORTHO-CLINICAL DIAGNOSTICS
ATTN: SUSAN WERNER WERNER
100 INDIGO CREEK DRIVE
ROCHESTER, NY 14626-5101

510(k) NO: K012561
PHONE NO : 716-453-4469

DEVICE: VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV CONTROLS
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORTHO-CLINICAL DIAGNOSTICS, INC.
TROS CHEMISTRY PRODUCTS CALIBRATOR KIT 2
ATTN: MARLENE A SHULMAN
100 INDIGO CREEK DR.
ROCHESTER, NY 14626-5101

510(k) NO: K012593
PHONE NO : 716-453-4041

DEVICE: VITROS CHEMISTRY PRODUCTS MAGNETIC HDL-CHOLESTEROL REAGENT, VI

SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORTHOMATRIX, INC.
ATTN: BEN SHAPPLEY
711 CHANEY COVE
COLLIERVILLE, TN 38017

510(k) NO: K010738
PHONE NO : 901-888-5614

DEVICE: CANNULATED PLUS SCREW SYSTEM
SE DECISION MADE: 01-AUG-2001
510(k) STATEMENT

ORTHOSCAN LTD.
ATTN: SHOSHANA FRIEDMAN
17 AHUZAH ST.
RA'ANANNA,

510(k) NO: K011827
PHONE NO : 972 977 18130

DEVICE: ORTELIUS 800
SE DECISION MADE: 28-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ORTHOTEC,LLC
ATTN: KAREN E WARDEN
8202 SHERMAN ROAD
CHESTERLAND, OH 44026

510(k) NO: K011807
PHONE NO : 440-729-8457

DEVICE: SCS CLARIS SPINAL SCREWS, TYPES V,G,E
SE DECISION MADE: 07-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

OSI MEDICAL, INC. AND ACCESSORIES ATTN: JON WERNER 13801 MCCORMICK DRIVE TAMPA, FL 33626	510(k) NO: K012533 PHONE NO : 813-818-7488	DEVICE: MODIFICATION TO OSI MEDICAL DOLPHIN STAND-ALONE PULSE OXIMETER SE DECISION MADE: 22-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
OSTEOMEDICS, INC. ATTN: ALBERT ENAYATI 809 CARTER LANE PARAMUS, NJ 07652	510(k) NO: K010118 PHONE NO : 201-444-7306	DEVICE: NORMED MANDIBULAR FIXATION SYSTEM SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
OWEN MUMFORD, LTD. ATTN: ROBERT SHAW 1755 A WEST OAK COMMONS COURT MARIETTA, GA 30062	510(k) NO: K011951 PHONE NO : 770-977-2226	DEVICE: EZ SYRINGE SE DECISION MADE: 02-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
PACEART, INC. ATTN: GEORGE MYERS 377 ROUTE 17 SOUTH HASBROUCK HEIGHTS, NJ 07604	510(k) NO: K012407 PHONE NO : 201-727-1703	DEVICE: PACEART TX3 CARDIAC EVENT RECORDER SE DECISION MADE: 14-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
PALOMAR MEDICAL TECHNOLOGIES, INC. ATTN: MARCY MOORE 131 KELEKENT LANE CARY, NC 27511	510(k) NO: K011747 PHONE NO : 919-363-2432	DEVICE: PALOMAR LC 100 DIODE LASER SE DECISION MADE: 30-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
PERSYST DEVELOPMENT CORP. ATTN: SCOTT B WILSON 316 SKYLINE DR. PRESCOTT, AZ 86303	510(k) NO: K011397 PHONE NO : 520-708-0705	DEVICE: PERSYST REVEAL SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
PHOTO MEDEX, , INC. ATTN: BOB ROSE 2431 IMPALA DR. CARLSBAD, CA 92008-7227	510(k) NO: K011382 PHONE NO : 760-602-3300	DEVICE: XTRAC EXCIMER LASER SYSTEM, MODEL AL 7000 SE DECISION MADE: 02-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
POLYMEDCO, INC. ATTN: HELLEN LANDICHO 510 FURNACE DOCK RD. CORTLANDT MANOR, NY 10567	510(k) NO: K012163 PHONE NO : 425-814-1514	DEVICE: POLYTITER SYSTEM SE DECISION MADE: 20-AUG-2001 510(k) STATEMENT
PRAXSYS BIOSYSTEMS, INC. ATTN: RICHARD M THAYER 12945 ALCOSTA BLVD. SAN RAMON, CA 94583-1323	510(k) NO: K011527 PHONE NO : 925-866-2121	DEVICE: PRAXSYS RELIA TSH TEST SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

PROGRESSIVE OPTICAL RESEARCH LTD.
ATTN: NICK NOVICKY
#20, 1410-40TH AVENUE, N.E.
CALGARY, ALBERTA,

510(k) NO: K010454
PHONE NO : 403 250 1181

DEVICE: THE ALBERTA LENS SM2, SULFOCON B
SE DECISION MADE: 01-AUG-2001
510(k) STATEMENT

PT. SUGIH INSTRUMENDO ABADI
ATTN: RICHARD GRAVER
933A MOTOR PARKWAY
HAUPPAUGE, NY 11788

510(k) NO: K012444
PHONE NO : 631-582-7320

DEVICE: ABN ANEROID SPHYGMOMANOMETER
SE DECISION MADE: 16-AUG-2001
510(k) STATEMENT

RADIUS MEDICAL TECHNOLOGIES, INC.
ATTN: MAUREEN FINLAYSON
63 GREAT RD.
MAYNARD, MA 01754

510(k) NO: K011759
PHONE NO : 978-897-6469

DEVICE: RADIUS NEXT GENERATION GUIDEWIRE
SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

RANDOX LABORATORIES, LTD.
ATTN: P. ARMSTRONG
ARDMORE, DIAMOND ROAD
CRUMLIN, CO. ANTRIM,

510(k) NO: K012319
PHONE NO : 44 289 4422413

DEVICE: RANDOX HUMAN ASSSAYED DRUG CONTROL
SE DECISION MADE: 24-AUG-2001
510(k) STATEMENT

RANFAC CORP.
XX THROW
ATTN: GEORGE J HATTUB
30 DOHERTY AVE., P.O. BOX 635
AVON INDUSTRIAL PARK
AVON, MA 02322

510(k) NO: K012224
PHONE NO : 508-588-4400

DEVICE: SINGLE ACTION BIOPSY NEEDLE, MODEL RCBS: XX GAUGE, XX LENGTH,

SE DECISION MADE: 22-AUG-2001

510(k) STATEMENT

RELIANCE MEDICAL CORP.
ATTN: ROBERT W NICKS
730 INDEPENDENT AVE.
GRAND JUNCTION, CO 81505

510(k) NO: K012044
PHONE NO : 970-986-5345

DEVICE: BI-PHASIC INFILTRATOR
SE DECISION MADE: 28-AUG-2001
510(k) STATEMENT

RICHARD WOLF MEDICAL INSTRUMENTS C
CCD ENDOCAM, SIOS-INTERFACE FOR LAPARO CO2 INSUFFLATOR
ATTN: ROBERT L CASARSA
353 CORPORATE WOODS PKWY.
VERNON HILLS, IL 60061

510(k) NO: K002328
PHONE NO : 847-913-1113

DEVICE: SIOS-INTERFACE FOR AUTO LIGHT PROJECTOR, SIOS-INTERFACE FOR 3

SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

RICHARD WOLF MEDICAL INSTRUMENTS C
NSERTS, ATTCHEMENTS, AND FORCEPS MODEL 8650, 8652, 8660
ATTN: ROBERT L CASARSA
353 CORPORATE WOODS PARKWAY
VERNON HILLS, IL 60061

510(k) NO: K011496
PHONE NO : 847-913-1113

DEVICE: CYSTO-URETHROSCOPES E-LINE EXISTING OF: SHEATHS, OBTURATORS, I

SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

RITE-DENT MANUFACTURING CORP.
ATTN: CESAR E VELIZ
1056 EAST 33RD ST.
HIALEAH, FL 33013-3526

510(k) NO: K011822
PHONE NO : 305-693-8626

DEVICE: PIT AND FISSURE CHEMICAL CURING SEALANT
SE DECISION MADE: 07-AUG-2001
510(k) STATEMENT

ROCHE DIAGNOSTICS CORP.
ATTN: MIKE FLIS
9115 HAGUE ROAD
P.O. BOX 50457
INDIANAPOLIS, IN 46250-0457

510(k) NO: K012210
PHONE NO : 800-428-5074

DEVICE: MODIFICATION TO ACCU-CHEK INFORM METER
SE DECISION MADE: 09-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
ION
ATTN: SHERRI L COENEN
9115 HAGUE ROAD
INDIANAPOLIS, IN 46250-0457

510(k) NO: K012286

PHONE NO : 317-521-3831

DEVICE: MODIFICATION TO:COBAS INTEGRA HDL-CHOLESTEROL PLUS 2ND GENERAI

SE DECISION MADE: 08-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
TION
ATTN: SHERRI L COENEN
9115 HAGUE ROAD
INDIANAPOLIS, IN 46250-0457

510(k) NO: K012287

PHONE NO : 317-521-3831

DEVICE: MODIFICATION TO: COBAS INTEGRA LDL-CHOLESTEROL PLUS 2ND GENERA

SE DECISION MADE: 07-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
ATTN: SHERRI L COENEN
9115 HAGUE ROAD
INDIANAPOLIS, IN 46250-0457

510(k) NO: K012399
PHONE NO : 317-521-3831

DEVICE: MODIFICATION TO ELECSYS FSH II CALSET
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ROSS PRODUCTS
ATTN: DANIEL HAMILTON
625 CLEVELAND AVENUE
COLUMBUS, OH 43215-1724

510(k) NO: K011467
PHONE NO : 614-624-3743

DEVICE: ROSS EMBRACE PUMP SET
SE DECISION MADE: 10-AUG-2001
510(k) STATEMENT

RUSCH INTL.
ATTN: JULIE A BEAUMONT
50 PLANTATION DRIVE
JAFFERY, NH 03452

510(k) NO: K011210
PHONE NO : 603-532-0204

DEVICE: THE PERCUQUICK SET FOR PERCUTANEOUS DILATION TRACHEOSTOMY
SE DECISION MADE: 15-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SADLER ELECTRONICS
ATTN: C A SADLER
3 COETZENBERG ROAD
EDGEMEAD,

510(k) NO: K010203
PHONE NO : 272 155 84088

DEVICE: ACCU-PULSE TENS UNIT
SE DECISION MADE: 28-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SALTON, INC.
ATTN: GEORGIA C RAVITZ
1050 CONNECTICUT AVE., NW
WASHINGTON, DC 20036-5339

510(k) NO: K011935
PHONE NO : 202-857-8939

DEVICE: REJUVENIQUE MODEL #RJV10
SE DECISION MADE: 08-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SEDECAL USA, , INC.
ATTN: DANIEL KAMM
P.O. BOX 7007
DEERFIELD, IL 60015

510(k) NO: K012663
PHONE NO : 847-374-1727

DEVICE: EASY MOVING MOBILE X-RAY UNIT (MODEL SM-HF)
SE DECISION MADE: 31-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SEIKAGAKU CORP.
ATTN: JOHN J SHEA
90 POTESKEET TRAIL
KITTY HAWK, NC 27949
510(k) NO: K011544
PHONE NO : 252-261-4158
DEVICE: HADGEL, 4 GRAM/SYRINGE
SE DECISION MADE: 15-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SEIN ELECTRONICS CO., LTD.
ATTN: WON. KY KIM
133-3, PYUNGCHON-DONG
ANYANG-CITY, KYUNGGI-DO,
510(k) NO: K012054
PHONE NO : 82 31 4210389
DEVICE: FULL AUTO WRIST DIGITAL BLOOD PRESSURE MONITOR, MODEL SE-312
SE DECISION MADE: 08-AUG-2001
510(k) STATEMENT

SEMPERMED USA, INC.
SS
ATTN: KATIE LEVINSON
30798 US HWY. 19 NORTH
PALM HARBOR, FL 34684
510(k) NO: K011749
PHONE NO : 727-787-7250
DEVICE: LATEX POWDERED PATIENT EXAMINATION GLOVE, 200 MICROGRAMS OR LE
SE DECISION MADE: 22-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SENSORMEDICS CORP.
ATTN: LINDA MURDOCK
22705 SAVI RANCH PKWY.
YORBA LINDA, CA 92887-4645
510(k) NO: K012085
PHONE NO : 714-283-2228
DEVICE: SOMNO STAR & SERIES SLEEP SYSTEM
SE DECISION MADE: 02-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIEMENS MEDICAL SYSTEMS, INC.
ATTN: PRAVEEN NADKARNI
186 WOOD AVENUE SOUTH
ISELIN, NJ 08830
510(k) NO: K011447
PHONE NO : 732-321-4950
DEVICE: IN SPACE 3D
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIEMENS MEDICAL SYSTEMS, INC.
ATTN: PENELOPE H GRECO
16 ELECTRONICS AVE.
DANVERS, MA 01923
510(k) NO: K012461
PHONE NO : 978-907-7500
DEVICE: SIEMENS INFINITY MIB II DUO PROTOCOL CONVERTER
SE DECISION MADE: 17-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIMS PORTEX LTD.
T 17G, MODELS MEONS 1633S, MEONS 1733S
ATTN: CLAIRE MULLINS
HYTHE
HYTHE, KENT,
510(k) NO: K012068
PHONE NO : 443 032 60551
DEVICE: WALLACE OOCYTE RETRIEVAL SETS 16G, WALLACE OOCYTE RETRIEVAL SE
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SKYLARK DEVICE & SYSTEMS CO., LTD
ATTN: GEORGE K.C. CHEN
34 CHUNG SHAN NORTH RD.,
12TH FL., SEC. 3
TAIPEI,
510(k) NO: K002832
PHONE NO : 011 886 225979005
DEVICE: CONDUCTIVE GEL FOR ULTRASOUND
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

SOREDEX INSTRUMENTATION CORPORATIO
ATTN: KAI LANER
NILSIANATU 10-14
HELSINKI,
510(k) NO: K012170
PHONE NO : 358 939 371
DEVICE: DIGORA PCT
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SPACELABS BURDICK, INC.
ATTN: JOHN E GREENBAUM
20310 SW 48TH STREET
FT. LAUDERDALE, FL 33332

510(k) NO: K011339
PHONE NO : 954-680-2548

DEVICE: QUEST EXERCISE STRESS SYSTEM, MODEL CONFIGURATION 14
SE DECISION MADE: 20-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SPECTRUM BIOTECH, INC.
ATTN: IAN MCDOUGALL
821 EAST 17TH STREET
N.VANCOUVER, BRITISH COLUMBIA,

510(k) NO: K003555
PHONE NO : 604 831 9311

DEVICE: SOLO-SAFE SAFETY SYRINGE, SIZE-3CC
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SID MFG., INC.
ATTN: STEPHEN M PALUMBO
1063 TURNPIKE ST.
P.O. BOX 420
STOUGHTON, MA 02072

510(k) NO: K012362
PHONE NO : 781-828-4400

DEVICE: MODIFICATION TO VASCULAR CLOSURE DEVICE
SE DECISION MADE: 23-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

STERITEC PRODUCTS, INC.
ATTN: LINDA NELSON
599 TOPEKA WAY, SUITE 700
CASTLE ROCK, CO 80104

510(k) NO: K010534
PHONE NO : 303-660-4201

DEVICE: CROSS-CHECKS DUAL, MODEL CI 125
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

STERLING MEDIVATIONS, INC.
ATTN: JOEL S DOUGLAS
25285 LA LOMA DR.
LOS ALTOS HILLS, CA 94022-4583

510(k) NO: K012330
PHONE NO : 650-949-0470

DEVICE: SIMPLICITY EURO QD INFUSION SET
SE DECISION MADE: 10-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

STRAUMANN USA
ATTN: LINDA JALBERT
RESERVOIR PLACE,
1601 TRAPELO ROAD
WALTHAM, MA 02154

510(k) NO: K012757
PHONE NO : 800-448-8168

DEVICE: ITI DENTAL IMPLANT SYSTEM
SE DECISION MADE: 22-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

STRYKER CORP.
ATTN: NICOLE PETTY
4100 EAST MILHAM AVENUE
KALAMAZOO, MI 49001-6197

510(k) NO: K010204
PHONE NO : 616-323-7700

DEVICE: STRYKER NAVIGATION SYSTEM-KNEE MODULE
SE DECISION MADE: 31-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SULZER INTRATHERAPEUTICS, INC.
CHNOLOGY
ATTN: MARIA E BRITTLE
651 CAMPUS DR.
ST. PAUL, MN 55112-3495

510(k) NO: K012066

PHONE NO : 651-697-2018

DEVICE: PROTEGE SELF-EXPANDING NITINOL STENT WITH STARPORT DELIVERY TE

SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SULZER INTRATHERAPEUTICS, INC.
CHNOLOGY
ATTN: MARCIA R ELLIS
651 CAMPUS DR.
ST. PAUL, MN 55112-3495

510(k) NO: K012347

PHONE NO : 651-697-4807

DEVICE: PROTEGE SELF-EXPANDING NITINOL STENT WITH STARPORT DELIVERY TE

SE DECISION MADE: 23-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SULZER SPINE-TECH
ATTN: JANELL A COLLEY
7375 BUSH LAKE RD.
MINNEAPOLIS, MN 55439-2027
510(k) NO: K012305
PHONE NO : 952-830-6205
DEVICE: MODIFICATION TO: TRINICA ANTERIOR CERVICAL PLATE SYSTEM
SE DECISION MADE: 22-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SUNMAX ENTERPRISE SHANGHAI CO. LTD
ATTN: SUSAN D GOLDSTEIN-FALK
55 NORTHERN BLVD.
SUITE 200
GREAT NECK, NY 11021
510(k) NO: K011717
PHONE NO : 203-431-1511
DEVICE: SUNMAX BLUE NITRILE POWDERED EXAMINATION GLOVES
SE DECISION MADE: 14-AUG-2001

510(k) STATEMENT

SUNMAX ENTERPRISE SHANGHAI CO. LTD
ATTN: SUSAN D GOLDSTEIN-FALK
55 NORTHERN BLVD.
SUITE 200
GREAT NECK, NY 11021
510(k) NO: K011765
PHONE NO : 302-431-1511
DEVICE: SUNMAX BLUE NITRILE POWDER-FREE EXAMINATION GLOVE
SE DECISION MADE: 16-AUG-2001

510(k) STATEMENT

SURGI-VISION, INC.
ATTN: NANCY E TAYLOR
20 FIRSTFIELD RD. SUITE 200
GAITHERSBURG, MD 20878
510(k) NO: K011781
PHONE NO : 301-527-2000
DEVICE: INTERCEPT-URETHRAL MICROCOIL
SE DECISION MADE: 31-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYBRON DENTAL SPECIALTIES, INC.
ATTN: COLLEEN BOSWELL
1717 WEST COLLINS AVENUE
ORANGE, CA 92867
510(k) NO: K011798
PHONE NO : 714-516-7484
DEVICE: CORERESTORE 2
SE DECISION MADE: 14-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYBRON DENTAL SPECIALTIES, INC.
ATTN: COLLEEN BOSWELL
1717 WEST COLLINS AVENUE
ORANGE, CA 92867
510(k) NO: K012321
PHONE NO : 714-516-7484
DEVICE: POINT 4 FLOWABLE
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYBRON DENTAL SPECIALTIES, INC.
ATTN: COLLEEN BOSWELL
1717 WEST COLLINS AVENUE
ORANGE, CA 92867
510(k) NO: K012322
PHONE NO : 714-516-7484
DEVICE: OPTIBOND 2
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: MATTHEW M HULL
P.O. BOX 1766
1690 RUSSELL ROAD
PAOLI, PA 19301-1222
510(k) NO: K011458
PHONE NO : 610-647-9700
DEVICE: SYNTHES STRAIGHT WRIST FUSION PLATE, 170MM
SE DECISION MADE: 02-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: MATTHEW M HULL
1690 RUSSELL RD.
PAOLI, PA 19301
510(k) NO: K011978
PHONE NO : 610-647-9700
DEVICE: SYNTHES LCP PROXIMAL TIBIA PLATE
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYVA CO. 510(k) NO: K011878
DEVICE: EMIT (R) TOX SALICYLIC ASSAY, MODEL 7SO19UL, EMIT (R) TOX SALI
CYLIC ACID CALIBRATORS, MODEL 7S109UL
ATTN: SUSAN L COLLINS PHONE NO : 408-366-3908
SE DECISION MADE: 13-AUG-2001
20400 MARIANI AVE.
510(k) SUMMARY AVAILABLE FROM FDA
CUPERTINO, CA 95014

SYVA CO. 510(k) NO: K012257
DEVICE: EMIT II PLUS MONOCLONAL AMPHETAMINE/METHAMPHETAMINE ASSAY MODE
L OSR9C229
ATTN: SUSAN L COLLINS PHONE NO : 408-366-3840
SE DECISION MADE: 03-AUG-2001
20400 MARIANI AVE.
510(k) SUMMARY AVAILABLE FROM FDA
CUPERTINO, CA 95014

TENS CARE LTD. 510(k) NO: K011543
DEVICE: TENS CARE, MODEL XL-Y3
ATTN: BERNARD JOHN TREMAINE PHONE NO : 44 161 9804310
SE DECISION MADE: 31-AUG-2001
76, STOCKPORT ROAD
510(k) SUMMARY AVAILABLE FROM FDA
TIMPERLRY,

TERUMO CARDIOVASCULAR SYSTEMS CORP 510(k) NO: K012209
DEVICE: CAPIOX SP PUMP WITH X-COATING PRODUCT CODE: CXSP45X
ATTN: GARRY A COURTNEY PHONE NO : 800-283-7866
SE DECISION MADE: 15-AUG-2001
125 BLUE BALL ROAD
510(k) SUMMARY AVAILABLE FROM FDA
ELKTON, MD 21921

TERUMO MEDICAL CORP. 510(k) NO: K012646
DEVICE: TERUMO 30 GAUGE HYPODERMIC NEEDLE
ATTN: BARBARA SMITH PHONE NO : 410-392-7241
SE DECISION MADE: 27-AUG-2001
125 BLUE BALL ROAD
510(k) SUMMARY AVAILABLE FROM FDA
ELKTON, MD 21921

TG GROUP, INC. 510(k) NO: K012355
DEVICE: IMAGE-X SYSTEM
ATTN: WAYNE LEBEAU PHONE NO : 877 557 4888
SE DECISION MADE: 09-AUG-2001
3505 LAIRD RD.
UNIT 7
510(k) STATEMENT
MISSISSAUGA, ONTARIO,

THE ANSPACH EFFORT, INC. 510(k) NO: K011444
DEVICE: ANSPACH EMAX DRILL SYSTEM
ATTN: WILLIAM E ANSPACH PHONE NO : 561-627-1080
SE DECISION MADE: 08-AUG-2001
4500 RIVERSIDE DR.
510(k) SUMMARY AVAILABLE FROM FDA
PALM BEACH GARDENS, FL 33410

THE BINDING SITE, LTD. 510(k) NO: K012291
DEVICE: HUMAN IGG SUBCLASS LIQUID REAGENT KITS, PRODUCT CODE LK001.TA
ATTN: JAY GELLER PHONE NO : 310-449-1399
SE DECISION MADE: 20-AUG-2001
WEST TOWER, SUITE 4000
2425 WEST OLYMPIC BOULEVARD
510(k) STATEMENT
SANTA MONICA, CA 90404

THE BINDING SITE, LTD. 510(k) NO: K012292
DEVICE: HUMAN IGG SUBCLASS LIQUID REAGENT KITS, PRODUCT CODE LK001.TB
ATTN: JAY H GELLER PHONE NO : 310-449-1399
SE DECISION MADE: 31-AUG-2001
WEST TOWER, SUITE 4000
2425 WEST OLYMPIC BOULEVARD
510(k) STATEMENT
SANTA MONICA, CA 90404

THE BINDING SITE, LTD. ATTN: JAY H GELLER WEST TOWER, SUITE 4000 2425 WEST OLYMPIC BOULEVARD SANTA MONICA, CA 90404	510(k) NO: K012295 PHONE NO : 310-449-1399	DEVICE: HUMAN IGG SUBCLASS LIQUID REAGENT KITS, PRODUCT CODE NK001.T SE DECISION MADE: 20-AUG-2001 510(k) STATEMENT
THE BINDING SITE, LTD. ATTN: JAY H GELLER WEST TOWER, SUITE 4000 2425 WEST OLYMPIC BOULEVARD SANTA MONICA, CA 90404	510(k) NO: K012296 PHONE NO : 310-449-1399	DEVICE: HUMAN IGG SUBCLASS LIQUID REAGENT KITS, PRODUCT CODE LK001.T SE DECISION MADE: 31-AUG-2001 510(k) STATEMENT
THE KENDALL COMPANY ATTN: MICHAEL SPEARS 15 HAMPSHIRE ST. MANSFIELD, MA 02048	510(k) NO: K011941 PHONE NO : 508-261-8155	DEVICE: EXCILON AMD ANTIMICROBIAL SPONGE MODEL #7088 SE DECISION MADE: 22-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
THE OLYMPUS OPTICAL CO. ATTN: LAURA STORMS-TYLER TWO CORPORATE CENTER DRIVE MELVILLE, NY 11747	510(k) NO: K012073 PHONE NO : 631-844-5688	DEVICE: OLYMPUS SPRAY CATHETER PW-6C-1 SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
THE RX FILES CORP. ATTN: YOLANDA SMITH P.O. BOX 4341 CROFTON, MD 21114	510(k) NO: K011571 PHONE NO : 410-451-0639	DEVICE: TRXF INTELLIGENT DOSING SYSTEM (IDS) -DOSING CALCULATOR SUITE SE DECISION MADE: 09-AUG-2001 510(k) STATEMENT
THERMO-ELECTRIC CO. ATTN: LAWRENCE E MADSON 455 RT. 30 IMPERIAL, PA 15126	510(k) NO: K011768 PHONE NO : 724-695-1890	DEVICE: THERMO-THERAPY, MODELS TT-101, TT-201, AND TT-202 SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
TORNIER S.A. ATTN: IRENE GOSSET ZIRST-161, RUE LAVOISIER MONTBONNOT,	510(k) NO: K012212 PHONE NO : 00 33 476613500	DEVICE: MODIFICATION TO AEQUALIS SHOULDER SYSTEM SE DECISION MADE: 15-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
TOSOH MEDICS, INC. ATTN: LOIS NAKAYAMA 347 OYSTER POINT BLVD., SUITE 201 SOUTH SAN FRANCISCO, CA 94080	510(k) NO: K010796 PHONE NO : 650-615-4970	DEVICE: AIA-PACK BRCA, ST AIA PACK BRCA SE DECISION MADE: 16-AUG-2001 510(k) STATEMENT
TRANSWORLD MOBILITY DISTRIBUTION, ATTN: JUAN C RIVERA 6140 MILD METRO DRIVE SUITE #6 FORT MYERS, FL 33912	510(k) NO: K011744 PHONE NO : 941-275-6767	DEVICE: HP-5, BATTERY OPERATED, REAR WHEEL DRIVE, POWER WHEELCHAIR SE DECISION MADE: 24-AUG-2001 510(k) STATEMENT

TRANSWORLD MOBILITY DISTRIBUTION,
ATTN: JUAN C RIVERA
6140 MILD METRO DRIVE
SUITE #6
FORT MYERS, FL 33912

510(k) NO: K011745
PHONE NO : 941-458-9290

DEVICE: HP-3, BATTETRY OPERATED, FONT WHEEL DRIVE, POWER WHEELCHAIR
SE DECISION MADE: 30-AUG-2001

510(k) STATEMENT

TREK DIAGNOSTIC SYSTEMS, INC.
ATTN: CYNTHIA C KNAPP
29299 CLEMENS RD. SUITE 1-K
WESTLAKE, OH 44145

510(k) NO: K011803
PHONE NO : 800-216-9036

DEVICE: SENSITITIRE 18 - 24 HOURS SUSCEPTIBILITY PLATES
SE DECISION MADE: 15-AUG-2001
510(k) STATEMENT

TREK DIAGNOSTIC SYSTEMS, INC.
ATTN: CYNTHIA C KNAPP
29299 CLEMENS RD. SUITE 1-K
WESTLAKE, OH 44145

510(k) NO: K012151
PHONE NO : 800-216-9036

DEVICE: HAEMOPHILUS/STREPTOCOCCUS PNEUMONIAE (HP) MIC PLATE
SE DECISION MADE: 29-AUG-2001
510(k) STATEMENT

TREX ENTERPRISES CORP.
ATTN: PETER J MARTIN
10455 PACIFIC CENTER CT.
SAN DIEGO, CA 92121-4339

510(k) NO: K012379
PHONE NO : 858-875-2616

DEVICE: PDX-2000 PORTABLE DIGITAL X-RAY SYSTEM
SE DECISION MADE: 16-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

TIJ BIOMEDICAL, LLC.
ATTN: RICHARD JORTBERG
2885 AURORA AVENUE, SUITE 15
BOULDER, CO 80303

510(k) NO: K012220
PHONE NO : 303-444-5026

DEVICE: TAO EMBRYO TRANSFER CATHETER SYSTEM
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ULTRACELL MEDICAL TECHNOLOGIES, IN
ATTN: COLLEEN MARTIN
183 PROVIDENCE,
NEW LONDON TNPK
NORTH STONINGTON, CT 06359

510(k) NO: K012196
PHONE NO : 860-599-4883

DEVICE: ULTRACELL ABSORBENT STICK
SE DECISION MADE: 24-AUG-2001

510(k) STATEMENT

UNITED STATES SURGICAL, A DIVISION
ATTN: JENNIFER SCHUCK
150 GLOVER AVE.
NORWALK, CT 06856

510(k) NO: K012273
PHONE NO : 203-845-1552

DEVICE: SPIRAL RADIUS 90-D SST SYSTEM
SE DECISION MADE: 15-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

VAL MED CORP.
ATTN: HOWARD M HOLSTEIN, ESQ.
555 THIRTEENTH STREET N.W.
COLUMBIA SQUARE
WASHINGTON, DC 20004

510(k) NO: K010754
PHONE NO : 202-637-5839

DEVICE: NURSE'S ASSISTANT O.R. CONTROL SYSTEM
SE DECISION MADE: 15-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

VYSIS
ATTN: RUSSEL K ENNS
3100 WOODCREEK DR.
DOWNERS GROVE, IL 60515

510(k) NO: K011031
PHONE NO : 630-271-7040

DEVICE: VYSIS UROVYSION BLADDER CANCER RECURRENCE KIT
SE DECISION MADE: 03-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

W.H.P.M., INC. ATTN: FRAN WHITE 163 CABOT STREET BEVERLY, MA 01915	510(k) NO: K012284 PHONE NO : 978-927-3808	DEVICE: WH ACCU TEST PREGNANCY TEST SE DECISION MADE: 28-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WAKO CHEMICALS, USA, INC. ATTN: TONYA MALLORY 1600 BELLWOOD RD. RICHMOND, VA 23237	510(k) NO: K010332 PHONE NO : 800-992-9256	DEVICE: WAKO IMMUNOASSAY CALIBRATOR SET SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WALTER ABENDSCHEIN, M.D. ATTN: WALTER ABENDSCHEIN 5530 WISCONSIN AVENUE SUITE 705 CHEVY CHASE, MD 20815	510(k) NO: K011603 PHONE NO : 301-656-4317	DEVICE: VHS PEDIATRIC HIP SCREW SYSTEM SE DECISION MADE: 15-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WALTER LORENZ SURGICAL, INC. ATTN: TREVOR BYRD 11520 TRADEPORT DRIVE JACKSONVILLE, FL 32218-2480	510(k) NO: K002790 PHONE NO : 904-741-4400	DEVICE: ADD-ON CONDYLE SE DECISION MADE: 06-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WECK CLOSURE SYSTEMS ATTN: BRIAN YOUNG ONE WECK DR. RESEARCH TRIANGLE PARK, NC 27709	510(k) NO: K011660 PHONE NO : 919-361-4041	DEVICE: WECK CARDIAC PACING WIRES SE DECISION MADE: 21-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WELCH ALLYN PROTOCOL, INC. ATTN: DONALD M ABBEY 8500 S.W. CREEKSIDE PLACE BEAVERTON, OR 97008-7107	510(k) NO: K012451 PHONE NO : 800-289-2500	DEVICE: PROPAQ ENCORE MODELS 202, 204, 206; PROPAQ CS MODELS 242, 244, 246 SE DECISION MADE: 20-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WELCH ALLYN, INC. ATTN: DAVID A YOUNG 95 OLD SHOALS RD. ARDEN, NC 28704	510(k) NO: K012455 PHONE NO : 828-684-4895	DEVICE: WELCH ALLYN DURASHOCK BLOOD PRESSURE SYSTEM SE DECISION MADE: 17-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WIELAND EDELMETALLE GMBH & CO. ATTN: GERHARD POLZER SCHWENNINGER STRABE 13 PFORZHEIM,	510(k) NO: K012156 PHONE NO : 49 723 13705219	DEVICE: IMAGINE H.E. SE DECISION MADE: 16-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
WRP ASIA PACIFIC SDN. BHD. ATTN: YUE WAH CHOW LOT 1, JALAN 3, KAWASAN PERUSAHAAN BANDAR BARU SALAK TINGGI, SEPANG SELANGOR,	510(k) NO: K012048 PHONE NO : 60 3 87061486	DEVICE: POWDER FREE NEOPRENE EXAMINATION GLOVES, NON STERILE SE DECISION MADE: 16-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

WRP ASIA PACIFIC SDN. BHD.
ABELING CLAIM (50 MICROGRAMS OR LESS)
ATTN: YUE WAH CHOW
LOT 1, JALAN 3,
KAWASAN PERUSAHAAN BANDAR BARU
SALAK TINGGI, SEPANG SELANGOR,

510(k) NO: K012135
PHONE NO : 603 870 61486

DEVICE: POWDER FREE BROWN LATEX SURGICAL GLOVES WITH PROTEIN CONTENT L
SE DECISION MADE: 01-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

XIROS PLC
ATTN: JIM ROWLAND
28-30 BLENHEIM TERRACE
LEEDS,

510(k) NO: K002172
PHONE NO : 441 132 446946

DEVICE: POLY-TAPES (VARIOUS SIZES AND WOVEN CONSTRUCTION VARIANTS)
SE DECISION MADE: 28-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ATTN: GREG HOLLAND
,

510(k) NO: K012280
PHONE NO : 949-262-0411

DEVICE: TITANIUM COMPRESSION ANCHOR SYSTEM MODEL VERSION 2
510(k) STATEMENT: 17-AUG-2001

TOTAL 510(k)s THIS PERIOD	340
TOTAL WITH SUMMARIES	260
TOTAL WITH STATEMENTS	80