

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-AUG-2001 THROUGH 31-AUG-2001

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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
AESCLAP, 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

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AESCULAP, INC. E ATTN: STEVE REITZLER 13221 MARICOTTE PLACE SAN DIEGO, CA 92130	510(k) NO: K011372 PHONE NO : 619-977-1465	DEVICE: AESCULAP, INC. SAFIL QUICK SYNTHETIC ABSORBABLE SURGICAL SUTURE SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALLEGIANCE HEALTHCARE CORP. ATTN: ERICA SEIHI 1500 WAUKEGAN RD. MOGAW 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: SUPREMCAT 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

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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 ZANIOPOULOS 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 SHEATH 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 DENTIA
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 COLLECTION 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

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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 AVAILAABLE 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

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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 PREMOUNED STENT SYSTEM SE DECISION MADE: 17-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB, AG ATTN: RAINER BIRKENBACH AMMERHALSTRASSE 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, LTD 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. QUICKTEK 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

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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 BILIARY 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

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CORGENIX, INC. QUANTITATIVE TEST KIT ATTN: NANCI DEXTER 12061 TEJON ST. WESTMINSTER, CO 80234	510(k) NO: K012567 PHONE NO : 303-457-4345	DEVICE: MODIFICATION TO: READS ANTI-PHOSPHATIDYL SERINE IGG/IGM SEMI-C 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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DIAGNOSTIC PRODUCTS CORP. OO 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. OO 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 COURINEY 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 DENIAL 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 HEMON-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 SIEGAGNO 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

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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 O
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 LIBERTÀ
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: ORIHO VLC; ORIHO 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-NAIIS
SE DECISION MADE: 24-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

FRESENIUS MEDICAL CARE NORTH AMERICA
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

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GAMERO 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

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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 AVAILAABLE 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: GSTBP BLOOD PRESSURE CUFF
SE DECISION MADE: 17-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

GULF COAST HYPERBARICS, INC.
ATTN: JAMES W MCCARHY
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

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HEALTHFITNESS 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. OO DIAGNOSTIC ULTRASOUND SCANNER; ATTN: WALTER WEYBURN 660 WHITE PLAINS ROAD TARRYTOWN, NY 10591-5107	510(k) NO: K012239 SP-711 SONOPROBE SYSTEM 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, 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 HYGIEKIT SE DECISION MADE: 15-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
HORIZONS INIL. 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 ARLEMA 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

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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

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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

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 HARINETT
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: AVANIE 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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KARL STORZ ENDOSCOPY-AMERICA, INC. 510(k) NO: K010345
ATTN: JAMES A LEE PHONE NO : 310-338-8100
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600

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. 510(k) NO: K010785
ATTN: JAMES A LEE PHONE NO : 310-410-2769
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600

DEVICE: KSEA DION-GRACIA SET
SE DECISION MADE: 21-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KENCAP LTD. 510(k) NO: K011514
ATTN: MARTY DELIN PHONE NO : 973-962-4844
247 MARGARET KING AVENUE
RINGWOOD, NJ 07456

DEVICE: INSTRUMENTS FOR ONE TIME USE - DISPOSABLE
SE DECISION MADE: 13-AUG-2001
510(k) STATEMENT

KEYMED (MEDICAL & INDUSTRIAL EQUIP) 510(k) NO: K011725
ATTN: ROGER GRAY PHONE NO : 44 170 2444276
STOCK RD.
SOUTHEND-ON-SEA, ESSEX,

DEVICE: OLYMPUS SUCTION PUMP, MODEL KV-5
SE DECISION MADE: 31-AUG-2001
510(k) STATEMENT

KIS PRODUCTS 510(k) NO: K984380
ATTN: REUBEN HERTZ PHONE NO : 954-764-0270
2318 SEA ISLAND DR.
FT. LAUDERDALE, FL 33301

DEVICE: DISPO ETCH
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KIS PRODUCTS 510(k) NO: K993124
ATTN: REUBEN HERTZ PHONE NO : 954-764-4074
2318 SEA ISLAND DR.
FT. LAUDERDALE, FL 33301

DEVICE: DISPODRILL
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KIS PRODUCTS 510(k) NO: K993182
ATTN: REUBEN HERTZ PHONE NO : 954-764-4074
2318 SEA ISLAND DR.
FT. LAUDERDALE, FL 33301

DEVICE: DISPOPROPHY
SE DECISION MADE: 06-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

KMI KOLSTER METHODS, INC. 510(k) NO: K010702
ATTN: ALWIN H KOLSTER PHONE NO : 714-956-1964
1170 N. GILBERT ST.
ANAHEIM, CA 92801

DEVICE: XUB EXTERNAL ULTRASOUND
SE DECISION MADE: 09-AUG-2001
510(k) STATEMENT

LAB-INTERLINK, INC. 510(k) NO: K010500
ATTN: DEBORAH S KIPP PHONE NO : 402-595-3767
1011 SOUTH SADDLE CREEK RD.
OMAHA, NE 68106

DEVICE: AUTOMATED WORKCELL CONTROL SOFTWARE
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

LATEXX PARTNERS BHD. 510(k) NO: K011791
ATTN: CHRISTINA SMITH PHONE NO : 410-451-0639
PO BOX 4341
CROFTON, MD 21114

DEVICE: POWDER FREE NITRILE EXAMINATION GLOVES, VIOLET COLOR
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 MOGRATH 2400 CONDENSEA 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

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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MAINE STANDARDS CO. ATTN: CHRISTINE V BEACH 765 ROOSEVELT TRAIL WINDHAM, ME 04062-5365	510(k) NO: K012120 PHONE NO : 207-892-1300	DEVICE: VALIDATE CHEM 4 CALIBRATION VERIFICATION TEST SET, MODEL 10004 SE DECISION MADE: 20-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
MAINE STANDARDS CO. ATTN: CHRISTINE V BEACH 765 ROOSEVELT TRAIL WINDHAM, ME 04062-5365	510(k) NO: K012122 PHONE NO : 207-892-1300	DEVICE: VALIDATE CHEM 5 CALIBRATION VERIFICATION TEST SET, MODEL 10005 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 FREDERES
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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 TEMPORARY 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 NORIHLAND 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

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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, INC. 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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: NANJI 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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NEUROIRON 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: SMARIWAVE 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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NON-INVASIVE MONITORING SYSTEMS, 1510(k) NO: K012020 ATTN: ALLAN F BRACK 1840 WEST AVE. MIAMI BEACH, FL 33139	PHONE NO : 305-534-3694	DEVICE: RESPIEVENTS SOFTWARE IS EVENT DATA PROCESSING SOFTWARE FOR A PC 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. WALITAM, MA 02454-9141	510(k) NO: K012058 PHONE NO : 781-894-0800	DEVICE: STAT PROFILE PHOX PLUS I 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
OPUSIDENT 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: LARAIN 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

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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 O2/CO2 NASAL CANNULA SAMPLE LINE
SE DECISION MADE: 15-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

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

DEVICE: ORIHO DEVELOPMENT ORION-I EMF SYSTEM
SE DECISION MADE: 22-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

ORIHO-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

ORIHO-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

ORIHOMATRIX, INC.
ATTN: BEN SHAPPLEY
711 CHANEY COVE
COLLIERSVILLE, 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 AHUZZAH ST.
RA'ANANNA,

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

DEVICE: ORIELTIUS 800

SE DECISION MADE: 28-AUG-2001

510(k) SUMMARY AVAILABLE FROM FDA

ORIHOTEC, 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

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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: XIRAC 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

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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PROGRESSIVE OPTICAL RESEARCH LTD. 510(k) NO: K010454
ATTN: NICK NOVICKY PHONE NO : 403 250 1181
#20, 1410-40TH AVENUE, N.E.
CALGARY, ALBERTA,

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

PT. SUGIH INSTRUMENTO ABADI 510(k) NO: K012444
ATTN: RICHARD GRAVER PHONE NO : 631-582-7320
933A MOTOR PARKWAY
HAUPPAUGE, NY 11788

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

RADIUS MEDICAL TECHNOLOGIES, INC. 510(k) NO: K011759
ATTN: MAUREEN FINLAYSON PHONE NO : 978-897-6469
63 GREAT RD.
MAYNARD, MA 01754

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

RANDOX LABORATORIES, LTD. 510(k) NO: K012319
ATTN: P. ARMSTRONG PHONE NO : 44 289 4422413
ARDMORE, DIAMOND ROAD
CRUMLIN, CO. ANTRIM,

DEVICE: RANDOX HUMAN ASSAYED 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 510(k) NO: K002328
OCD ENDOCAM, SIOS-INTERFACE FOR LAPARO CO2 INSUFFLATOR
ATTN: ROBERT L CASARSA PHONE NO : 847-913-1113
353 CORPORATE WOODS PKWY.
VERNON HILLS, IL 60061

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 510(k) NO: K011496
NSERIS, ATTACHEMENTS, AND FORCEPS MODEL 8650, 8652, 8660
ATTN: ROBERT L CASARSA PHONE NO : 847-913-1113
353 CORPORATE WOODS PARKWAY
VERNON HILLS, IL 60061

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. 510(k) NO: K011822
ATTN: CESAR E VELIZ PHONE NO : 305-693-8626
1056 EAST 33RD ST.
HIALEAH, FL 33013-3526

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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 GENERATION 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 GENERATION 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 AVAILAABLE 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 EMERACE 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 EDGE MEAD,	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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 CORPORATION ATTN: KAI LANER NILSIANAU 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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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 MCDUGALL
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

STD 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 BRITILE
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

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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SULZER SPINE-TECH
ATTN: JANELLE 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 DENIAL 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 DENIAL 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 DENIAL 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

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SYVA CO. CYLIC ACID CALIBRATORS, MODEL 7S109UL ATTN: SUSAN L COLLINS 20400 MARIANI AVE. CUPERTINO, CA 95014	510(k) NO: K011878 PHONE NO : 408-366-3908	DEVICE: EMIT (R) TOX SALICYLIC ASSAY, MODEL 7S019UL, EMIT (R) TOX SALI SE DECISION MADE: 13-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. L OSR9C229 ATTN: SUSAN L COLLINS 20400 MARIANI AVE. CUPERTINO, CA 95014	510(k) NO: K012257 PHONE NO : 408-366-3840	DEVICE: EMIT II PLUS MONOCLONAL AMPHETAMINE/METHAMPHETAMINE ASSAY MODE SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
TENS CARE LTD. ATTN: BERNARD JOHN TREMAINE 76, STOCKPORT ROAD TIMPERLRY,	510(k) NO: K011543 PHONE NO : 44 161 9804310	DEVICE: TENS CARE, MODEL XL-Y3 SE DECISION MADE: 31-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
TERUMO CARDIOVASCULAR SYSTEMS CORP ATTN: GARRY A COURNEY 125 BLUE BALL ROAD ELKTON, MD 21921	510(k) NO: K012209 PHONE NO : 800-283-7866	DEVICE: CAPIOX SP PUMP WITH X-COATING PRODUCT CODE: CXSP45X SE DECISION MADE: 15-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
TERUMO MEDICAL CORP. ATTN: BARBARA SMITH 125 BLUE BALL ROAD ELKTON, MD 21921	510(k) NO: K012646 PHONE NO : 410-392-7241	DEVICE: TERUMO 30 GAUGE HYPODERMIC NEEDLE SE DECISION MADE: 27-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
TG GROUP, INC. ATTN: WAYNE LEBEAU 3505 LAIRD RD. UNIT 7 MISSISSAUGA, ONTARIO,	510(k) NO: K012355 PHONE NO : 877 557 4888	DEVICE: IMAGE-X SYSTEM SE DECISION MADE: 09-AUG-2001 510(k) STATEMENT
THE ANSPACH EFFORT, INC. ATTN: WILLIAM E ANSPACH 4500 RIVERSIDE DR. PALM BEACH GARDENS, FL 33410	510(k) NO: K011444 PHONE NO : 561-627-1080	DEVICE: ANSPACH EMAX DRILL SYSTEM SE DECISION MADE: 08-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
THE BINDING SITE, LTD. ATTN: JAY GELLER WEST TOWER, SUITE 4000 2425 WEST OLYMPIC BOULEVARD SANTA MONICA, CA 90404	510(k) NO: K012291 PHONE NO : 310-449-1399	DEVICE: HUMAN IGG SUBCLASS LIQUID REAGENT KITS, PRODUCT CODE LK001.TA 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: K012292 PHONE NO : 310-449-1399	DEVICE: HUMAN IGG SUBCLASS LIQUID REAGENT KITS, PRODUCT CODE LK001.TB SE DECISION MADE: 31-AUG-2001 510(k) STATEMENT

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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 AEGUALIS 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

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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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, BATTERY OPERATED, FRONT 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: SENSITIVE 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
TTU BIOMEDICAL, LLC. ATTN: RICHARD JORPBERG 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, INC. ATTN: COLLEEN MARTIN 183 PROVIDENCE, NEW LONDON TPK 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 UROVISION BLADDER CANCER RECURRENCE KIT SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

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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. 246 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, 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 STRASSE 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

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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 I 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

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TOTAL WITH SUMMARIES	260
TOTAL WITH STATEMENTS	80