

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-OCT-2000 THROUGH 31-OCT-2000

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3D LINE USA, INC.
ATTN: KAREN H RIGAMONTI
2807 OLD COURT ROAD
BALTIMORE, MD 21208

510(k) NO: K001163
PHONE NO : 410-580-1730

DEVICE: DMLC IV-ERGO
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: JILL N SACKETT
D-389, BLDG. AP30
200 ABBOTT PARK ROAD
ABBOTT PARK, IL 60064-6157

510(k) NO: K000886
PHONE NO : 847-937-4085

4612 '00 NOV 15 19:51
DEVICE: SPIROL EPIDURAL CATHETER
SE DECISION MADE: 05-OCT-2000

510(k) STATEMENT

ABX DIAGNOSTICS, INC.
ATTN: BRUCE DAVIS
34 BUNSEN DR.
IRVINE, CA 92618

510(k) NO: K002646
PHONE NO : 297-842-7914

DEVICE: ABX MICROS CRP
SE DECISION MADE: 26-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ACRYMED, INC.
ATTN: BRUCE GIBBINS
12232 SW GARDEN PLACE
PORTLAND, OR 97223

510(k) NO: K002909
PHONE NO : 503-624-9830

DEVICE: ACRYDERM SILVER ANTIMICROBIAL STRANDS MODEL A-020103
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC.
ATTN: JOYCE THOMAS
3773 EXECUTIVE CENTER PARKWAY
CENTER VALLEY, PA 18034

510(k) NO: K002871
PHONE NO : 610-231-0228

DEVICE: MODIFICATION TO YASARGIL ANEURYSM CLIPS
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES, INC.
ATTN: MIKE HUDON
3000 MINUTEMAN RD.
ANDOVER, MA 01810-1099

510(k) NO: K002967
PHONE NO : 978-659-3173

DEVICE: M2376A DEVICELINK SYSTEM, MODEL M2376A
SE DECISION MADE: 18-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES, INC.
ATTN: MIKE HUDON
3000 MINUTEMAN RD.
ANDOVER, MA 01810-1099

510(k) NO: K003107
PHONE NO : 978-659-3173

DEVICE: M2376A DEVICELINK SYSTEM
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

AIR FORCE INC
1
ATTN: PIERO POLICICCHIO
933 BUTTERNUT DRIVE
HOLLAND, MI 49424

510(k) NO: K001493
PHONE NO : 619-399-8511

DEVICE: DENTAL AIR FORCE HOME DENTAL CLEANING SYSTEM, MODEL NO. 002000
SE DECISION MADE: 25-OCT-2000
510(k) STATEMENT

AIRSEP CORP.
ATTN: PETER WEISENBORN
290 CREEKSIDE DR.
BUFFALO, NY 14228-2070

510(k) NO: K000963
PHONE NO : 716-691-0202

DEVICE: DA VINCHI EEG AND EMG/EP SYSTEMS
SE DECISION MADE: 20-OCT-2000
510(k) STATEMENT

945-0120

LST 100

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ALCON UNIVERSAL, LTD. ATTN: MICHAEL E PFLEGER 6201 SOUTH FREEWAY FORT WORTH, TX 76134-2099	510(k) NO: K002589 PHONE NO : 817-551-4877	DEVICE: OPTI-FREE EXPRESS MULTI-PURPOSE DISINFECTING SOLUTION SE DECISION MADE: 23-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN MEDICAL SYSTEMS, INC. ATTN: ELSA A LINKE 10700 BREN RD., WEST MINNETONKA, MN 55343	510(k) NO: K002919 PHONE NO : 952-930-6309	DEVICE: AMS SPHINCTER 800 URINARY PROSTHESIS SE DECISION MADE: 03-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
ANGIODYNAMICS, INC. ATTN: TERI JUCKETT 603 QUEENSBURY AVE. QUEENSBURY, NY 12804	510(k) NO: K001578 PHONE NO : 518-798-1215	DEVICE: ANGIODYNAMICS SOFT-VU HYDROPHILIC COATED ANGIOGRAPHIC CATHETER SE DECISION MADE: 13-OCT-2000 510(k) STATEMENT
ARISTA LATINDO INDUSTRIAL, LTD. ATTN: LINGA SUMARIA 128 JALAN KYAI HAJI MUHAMMAD MANSYUR JAKARTA BARAT,	P. 510(k) NO: K002745 PHONE NO : 622 166 20201/195	DEVICE: VINYL EXAMINATION GLOVES, POWDER FREE, BLUE COLOR SE DECISION MADE: 12-OCT-2000 510(k) STATEMENT
ARISTA LATINDO INDUSTRIAL, LTD. ATTN: LINGA SUMARIA 128 JALAN KYAI HAJI MUHAMMAD MANSYUR JAKARTA BARAT,	P. 510(k) NO: K002746 PHONE NO : 622 166 20201/195	DEVICE: VINYL EXAMINATION GLOVES, POWDER FREE, VANILLA COLOR SE DECISION MADE: 11-OCT-2000 510(k) STATEMENT
ARROW INIL., INC. PROTECTION ATTN: THOMAS D NICKEL 2400 BERNVILLE RD. READING, PA 19605	510(k) NO: K003006 PHONE NO : 610-478-3137	DEVICE: TWO-LUMEN PICC WITH BLUE FLEXTIP CATHETER AND INTEGRAL NEEDLE SE DECISION MADE: 27-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
ATOM MEDICAL CORPORATION ATTN: SHEILA HEMMON-HEYER 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K002355 PHONE NO : 508-643-0434	DEVICE: ATOM INFA WARMER V-505 SE DECISION MADE: 10-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
AUTOMATIC LIQUID PACKAGING, INC. ATTN: JOHN BRDA 2200 LAKE SHORE DR. WOODSTOCK, IL 60098	510(k) NO: K994321 PHONE NO : 815-338-9500	DEVICE: STERILE WATER AND 0.9% SODIUM CHLORIDE FOR IRRIGATION, USP SE DECISION MADE: 25-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
AVITRO LLC ATTN: JOHN BRDA 2200 LAKE SHORE DRIVE WOODSTOCK, IL 60098	510(k) NO: K000632 PHONE NO : 815-338-9500	DEVICE: 0.9% SODIUM CHLORIDE VASCULAT ACCESS DEVICE SE DECISION MADE: 19-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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AVITRO LLC ATTN: JOHN BRDA 2200 LAKE SHORE DRIVE WOODSTOCK, IL 60098	510(k) NO: K001795 PHONE NO : 815-338-9500	DEVICE: THE AVITRO LLC, 10 AND 100 USO UNITS/ML HEPARIN SODIUM VAFD SE DECISION MADE: 19-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
AXON SYSTEMS, INC. ATTN: HOWARD BAILIN 400-2200 OSER AVE. HAUPPAUGE, NY 11788	510(k) NO: K002316 PHONE NO : 800-888-2966	DEVICE: PHOENIX DIGITAL EEG SE DECISION MADE: 26-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
AXYA MEDICAL, INC. ATTN: HOWARD L SCHRAYER 100 CUMMINGS CENTER SUITE 444C BEVERLY, MA 01915	510(k) NO: K002557 PHONE NO : 609-924-9510	DEVICE: SUTURE WELDING SYSTEM AND KIT-(J-TIP DESIGN) SE DECISION MADE: 06-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB, INC. ATTN: PAUL G STAPLETON 1400 NORTH GOODMAN ST. ROCHESTER, NY 14603-0450	510(k) NO: K002823 PHONE NO : 716-338-8172	DEVICE: RENU MULTIPLUS MULTI-PURPOSE DISINFECTING SOLUTION SE DECISION MADE: 17-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
BAXTER HEALTHCARE CORP. ATTN: MARY ELLEN SNYDER RT. 120 AND WILSON ROAD ROUND LAKE, IL 60073-0490	510(k) NO: K003225 PHONE NO : 847-270-4644	DEVICE: SOLUTION ADMINISTRATION SETS WITH CAPLESS LUER ACTIVATED VALVE SE DECISION MADE: 19-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: WILLIAM J PIGNATO 63 NORTH ST. MEDFIELD, MA 02052-1688	510(k) NO: K002376 PHONE NO : 508-359-3825	DEVICE: ADVIA: CENTAUR AND ACS: 180 CPSA ASSAY SE DECISION MADE: 26-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
BAYLIS MEDICAL CO., INC. MENT CONNECTOR CABLE/PMX-BAY-BAY ATTN: KRIS SHAH 5160 EXPLORER DRIVE, UNIT 37 MISSISSAUGA,	510(k) NO: K002389 PHONE NO : 905 602 4875	DEVICE: BAYLIS PAIN MANAGEMENT PROBE/PMP-20-145 AND BAYLIS PAIN MANAGE SE DECISION MADE: 23-OCT-2000 510(k) STATEMENT
BECKMAN COULTER, INC. OO ATTN: ANNETTE HELLIE 200 SOUTH KRAEMER BLVD. BREA, CA 92822-8000	510(k) NO: K002799 PHONE NO : 714-993-8767	DEVICE: PARAGON CZE 2000 CAPILLARY ELECTROPHORESIS SYSTEM AND BUFFER-1 SE DECISION MADE: 05-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: MARA CALER 7330 CARROLL ROAD SAD DIEGO, CA 92196-9006	510(k) NO: K002905 PHONE NO : 858-621-4583	DEVICE: ACCESS THYROGLOBULIN REAGENTS ON THE ACCESS ANALYZER SE DECISION MADE: 19-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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BIO-VASCULAR, INC.
ATTN: DAISY P SIN
2575 UNIVERSITY AVE., STE.180
ST. PAUL, MN 55114-1024

510(k) NO: K002233
PHONE NO : 651-603-5203

DEVICE: BVI SLING
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOCARE CORP.
ATTN: PAUL W MCDONALD
200 PROSPECT STREET
WALTHAM, MA 02454

510(k) NO: K002855
PHONE NO : 781-894-0800

DEVICE: BIOLYTE 2000 NA+,K+,CL-/LI+ELECTROLYTE ANALYZER
SE DECISION MADE: 12-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOCHECK, INC.
ATTN: ROBIN J HELLEN
9418 LASAINE AVE
NORTHRIDGE, CA 91325

510(k) NO: K002294
PHONE NO : 818-709-5646

DEVICE: BIOCHECK TESTOSTERONE EIA, MODEL BC-1115
SE DECISION MADE: 02-OCT-2000
510(k) STATEMENT

BIOLOGICALLY ORIENTED PROSTHESES
ATTN: ANGENA PAREKH
17 SEVENTEENTH ST.
PORT HURON, MI 48060.

510(k) NO: K002325
PHONE NO : 810-982-7777

DEVICE: WUJIN #3 TIBIAL NAIL
SE DECISION MADE: 30-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BICMERIEUX, INC.
ATTN: JANET CONNOLLY
1022 HINGHAM STREET
ROCKLAND, MA 02370

510(k) NO: K001460
PHONE NO : 781-871-4442

DEVICE: VIDAS H. PYLORI IGG (HPY) ASSAY, MODEL 30 192
SE DECISION MADE: 04-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET ORTHOPEDICS, INC.
ATTN: PATRICIA SANDBORN BERES
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K002057
PHONE NO : 219-267-6639

DEVICE: BROOKER TIBIA NAILS
SE DECISION MADE: 04-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET ORTHOPEDICS, INC.
ATTN: PATRICIA SANDBORN BERES
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K002278
PHONE NO : 219-269-6639

DEVICE: BROOKER FEMORAL NAILS
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: TRACY BICKEL
56 EAST BELL DRIVE
WARSAW, IN 46582

510(k) NO: K002423
PHONE NO : 219-372-1761

DEVICE: LACTOSORB PUSH SCREW
SE DECISION MADE: 20-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: MICHELLE L MCKINLEY
AIRPORT INDUSTRIAL PARK,
P.O.BOX 587
WARSAW, IN 46580

510(k) NO: K002772
PHONE NO : 219-372-1644

DEVICE: ASCENT XXL CLOSED BOX FEMORAL COMPONENT
SE DECISION MADE: 04-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

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BIOMET, INC.
ATTN: TRACY J BICKE;
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K002998
PHONE NO : 219-372-1761

DEVICE: BIOMET BI-POLAR SHOULDER SYSTEM
SE DECISION MADE: 06-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

BIOPLATE, INC.
ATTN: ERIC V HOHENSTEIN
6911 MELROSE AVE.
LOS ANGELES, CA 90038

510(k) NO: K002879
PHONE NO : 323-549-9500

DEVICE: MODIFICATION TO BIOPLATE BIOCLIP CRANIOTOMY FIXATION SYSTEM
SE DECISION MADE: 05-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BIOPRO (M) SDN BHD
GLOVES (GREEN/ PURPLE)
ATTN: JAMES H LALE
LOT14, PT.4204 LINGKARN SULTAN
HISHAMUDDIN, NORTH PORT INDU.
PORT KLANG,

510(k) NO: K994276
PHONE NO : 603 376 1386

DEVICE: BIOPRO, NITRILON, CORRECT TOUCH- NITRILE POWDERED EXAMINATION
SE DECISION MADE: 20-OCT-2000
510(k) STATEMENT

BIOPRO (M) SDN BHD
GLOVES (GREEN, PURPLE)
ATTN: JAMES H LALE
LOT14, PT.4204 LINGKARN SULTAN
HISHAMUDDIN, NORTH PORT INDU.
PORT KLANG,

510(k) NO: K994281
PHONE NO : 603 376 1390

DEVICE: BIOPRO, NITRILE, CORRECT TOUCH NITRILE POWDER FREE EXAMINATION
SE DECISION MADE: 20-OCT-2000
510(k) STATEMENT

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

510(k) NO: K002133
PHONE NO : 508-652-5008

DEVICE: NIR BILLIARY STENT SYSTEM; MARSHAL BALLOON DILATATION CATHETER
SE DECISION MADE: 12-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ATTN: CAROL J HOLLOWAY
ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760

510(k) NO: K002802
PHONE NO : 508-650-8514

DEVICE: RAPID EXCHANGE TAPER TOME
SE DECISION MADE: 05-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

BRENNEN MEDICAL, INC.
ATTN: PHILLIP LAWIN
1290 HAMMOND RD.
ST. PAUL, MN 55110

510(k) NO: K002077
PHONE NO : 651-429-7413

DEVICE: GLUCANPRO CREAM
SE DECISION MADE: 02-OCT-2000
510(k) STATEMENT

BRENNEN MEDICAL, INC.
ATTN: PHILLIP LAWIN
1290 HAMMOND RD.
ST. PAUL, MN 55110

510(k) NO: K002078
PHONE NO : 651-429-7413

DEVICE: BETA GLUCAN GEL (MACROPRO GEL)
SE DECISION MADE: 02-OCT-2000
510(k) STATEMENT

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C.R. BARD, INC. ATTN: MARION GORDON 129 CONCORD RD., BLDG. 3 BILLERICA, MA 01821-7031	510(k) NO: K002094 PHONE NO : 978-262-4867	DEVICE: BARD MEMOTHERM COVERED ESOPHAGEAL STENT, MODEL MULTIPLE SE DECISION MADE: 06-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. ATTN: RUTH C FORSTADT 100 SOCKANOSSETT CROSSROAD CANSTON, RI 02920	510(k) NO: K002684 PHONE NO : 401-463-7000	DEVICE: COMPOSIX E/X MESH SE DECISION MADE: 11-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
CANTOR & SILVER LTD. OFT CONTACT LENSES ATTN: MARTIN DALSTING 623 GLACIER DRIVE GRAND JUNCTION, CO 81503	510(k) NO: K994320 PHONE NO : 970-243-5490	DEVICE: CHROMAGEN V2.0 HAPLOSCOPIC SYSTEM & COLOR VISION ENHANCEMENT S SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
CEDARA SOFTWARE CORPORATION Y CD VIEWER ATTN: CAROL NAKAGAWA 6509 AIRPORT RD. MISSISSAUGA, ONTARIO,	510(k) NO: K002590 PHONE NO : 905 672 2100	DEVICE: CEDARA CARDIOLOGY VIEWER, CARDIOLOGY ARCHIVE VIEWER, CARDIOLOG SE DECISION MADE: 31-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
CERAMOPTEC, INC. ATTN: CAROL J MORELLO 515 SHAKER ROAD EAST LONGMEADOW, MA 01028	510(k) NO: K002296 PHONE NO : 413-525-0600	DEVICE: CERALAS G15 532NM FREQUENCY DOUBLED ND:YAG LASER, MODEL G1-G15 SE DECISION MADE: 02-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
CIVCO MEDICAL INSTRUMENTS CO., INC. ATTN: J. WILLIAM JONES 102 FIRST ST. SOUTH KALONA, IA 52247	510(k) NO: K002546 PHONE NO : 319-656-4447	DEVICE: CIV-FLEX HOLSTER COVER, MODEL STERILE, LATEX-FREE SE DECISION MADE: 31-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
COGENT DIAGNOSTICS LTD. ATTN: DANIELE KNIGHT PENILANDS SCIENCE PARK BUSH LOAN, PENICUIK MIDLOTHIAN, SCOTLAND,	510(k) NO: K003054 PHONE NO : 714-933-3000	DEVICE: AUTOSTAT II ENA-6 PROFILE ELISA SE DECISION MADE: 13-OCT-2000 510(k) STATEMENT
COGENT DIAGNOSTICS LTD. ATTN: DANIELE KNIGHT PENILANDS SCIENCE PARK BUSH LOAN, PENICUIK MIDLOTHIAN, SCOTLAND,	510(k) NO: K003057 PHONE NO : 714-933-3000	DEVICE: AUTOSTAT II ENA-4 PROFILE ELISA SE DECISION MADE: 13-OCT-2000 510(k) STATEMENT
COMPUTERIZED MEDICAL SYSTEMS, INC. ATTN: MICHAEL A PARSONS 1145 CORPORATE LAKE DR. SUITE 100 ST. LOUIS, MO 63132-1716	510(k) NO: K002147 PHONE NO : 314-993-0003	DEVICE: FOCUS SE DECISION MADE: 13-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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COOK, INC.
ATTN: MARY GOSSARD
925 SOUTH CURRY PIKE
P.O. BOX 489
BLOOMINGTON, IN 47402

510(k) NO: K000855
PHONE NO : 812-339-2235

DEVICE: GUNTHER TULIP VENA CAVA MREYE FILTER SET
SE DECISION MADE: 18-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

CORDIS CORP.
ATTN: CHUCK RYAN
7 POWDERHORN DRIVE
WARREN, NJ 07059

510(k) NO: K003159
PHONE NO : 908-412-7446

DEVICE: CORDIS SLALOM PTA BALLOON CATHETER
SE DECISION MADE: 30-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

CORE-VENT CORP.
B 8,10,12,14/OP3.5D/OPAR,OPB 8,10,12,14/OP2.3D/OP2.8D,
ATTN: WILL FISHER
4630 SOUTH ARVILLE, SUITE D
LAS VEGAS, NV 89103

510(k) NO: K002188
PHONE NO : 702-253-1344

DEVICE: SWISSPLUS IMPLANT SYSTEM, MODEL SPWB 8,10,12,14/OPH20/SMPR, SP
SE DECISION MADE: 30-OCT-2000
510(k) STATEMENT

COUSIN BIOTECH S.A.R.L
ATTN: HOWARD M HOLSTEIN
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004-1109

510(k) NO: K002479
PHONE NO : 202-637-5813

DEVICE: BIOMESH P1 AND BIOMESH PLUG AND PATCH
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GTI PET SYSTEMS, INC.
ATTN: WILLIAM SKREMSKY
810 INNOVATION DR.
KNOXVILLE, TN 37932-2571

510(k) NO: K002715
PHONE NO : 865-218-2522

DEVICE: ECAT PET SCANNER
SE DECISION MADE: 31-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

CURON MEDICAL, INC.
, MODEL S500-ST
ATTN: THOMAS C WEHMAN
735 PALOMAR AVENUE
SUNNYVALE, CA 94086

510(k) NO: K002898
PHONE NO : 408-733-9910

DEVICE: CURON CONTROL MODULE ELECTROSURGICAL GENERATOR AND ACCESSORIES
SE DECISION MADE: 17-OCT-2000
510(k) STATEMENT

D.K.M. CO.,LTD.
ATTN: ANDREW PAENG
P.O. BOX 3415
ST. LOUIS, MO 63143

510(k) NO: K001668
PHONE NO : 573-225-7700

DEVICE: GLOBAL SPINAL FIXATION SYSTEM
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
TORS, MODEL 4G019UL, 4G109UL
ATTN: PAUL L ROGERS
3403 YEREA BUENA ROAD
P.O. BOX 49013
SAN JOSE, CA 95161-9013

510(k) NO: K002551
PHONE NO : 408-239-2309

DEVICE: EMIT 2000 VALPROIC ACID ASSAY, EMIT 2000 VALPROIC ACID CALIBRA
SE DECISION MADE: 11-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: REBECCA S AYASH
GLASGOW SITE
P.O. BOX 6101
NEWARK, DE 19714-6101

510(k) NO: K002804
PHONE NO : 302-631-6276

DEVICE: N PROTEIN STANDARD SL
SE DECISION MADE: 05-OCT-2000
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DADE BEHRING, INC. OPEN CALIBRATORS, MODEL 7A409UL ATTN: PAUL L ROGERS 3403 YEREA BUENA ROAD SAN JOSE, CA 95161-9013	510(k) NO: K002974 PHONE NO : 408-239-2309	DEVICE: EMIT TOX ACETAMINOPHEN ASSAY, MODEL 7A319UL; EMIT TOX ECETAMIN SE DECISION MADE: 11-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
DATASCOPE CORP. TO DATASCOPE PROFILE 8FR. IAB, 40CC ATTN: JOANNE WOLF 15 LAW DR. FAIRFIELD, NJ 07004-0011	510(k) NO: K002949 PHONE NO : 973-244-6100	DEVICE: MODIFICATION TO DATASCOPE PROFILE 8FR. IAB, 34CC; MODIFICATION SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
DATEX-OMEDA, INC. LOOA08 ATTN: JOEL C KENT 3 HIGHWOOD DR. TEWKSBURY, MA 01876	510(k) NO: K002478 PHONE NO : 978-640-0460	DEVICE: S/5 COMPACT ANESTHESIA MONITOR WITH S-00A05, S-00A06. L-00A07, SE DECISION MADE: 05-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
DEPILASE GROUP LTD. ATTN: MARIO LUCA RUSSO 12 ST. JAMES'S SQUARE LONDON SW1 Y 4RB,	510(k) NO: K001990 PHONE NO : 440 207 8496120	DEVICE: DEPILASE YAGLASE ND:YAG LASER SYSTEM AND ACCESSORIES SE DECISION MADE: 23-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
DEPUY ORTHOPAEDICS, INC. ATTN: CHERYL K HASTINGS 700 ORTHOPAEDIC DR. P.O. BOX 988 WARSAW, IN 46581-0988	510(k) NO: K002883 PHONE NO : 219-371-4901	DEVICE: PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS SE DECISION MADE: 13-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: PATRICIA FLOOD 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K002980 PHONE NO : 973-299-9022	DEVICE: MODIFICATION TO EBI ANTERIOR CERVICAL PLATE SYSTEM SE DECISION MADE: 23-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
ECLIPSE SYSTEMS INC. ATTN: ROSINA ROBINSON 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K002229 PHONE NO : 508-643-0434	DEVICE: WACKERS-LIU CQ SOFTWARE SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
EEMAGINE MEDICAL IMAGING SOLUTIONS ATTN: SCOTT PEASE W306 D8345 CHESNUT DRIVE MUKWONAGO, WI 53149	510(k) NO: K002631 PHONE NO : 262-363-5546	DEVICE: ELECTROENCEPHALOGRAPH SOFTWARE EEMAGINE EEG SE DECISION MADE: 23-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
ELECTRO MEDICAL SYSTEMS SA AL ATTN: SHEILA HEMMON-HEYER 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K002484 PHONE NO : 508-643-0460	DEVICE: EMS SWISS ORTHOCLAST CHISELS FOR NON-CEMENTED PROSTHESIS REMOV SE DECISION MADE: 04-OCT-2000 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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ENCORE ORTHOPEDICS, INC.
ATTN: JOANNA DROEGE
9800 METRIC BLVD.
AUSTIN, TX 78758

510(k) NO: K002959
PHONE NO : 512-834-6255

DEVICE: MODIFICATION TO ISOBAR SPINAL SYSTEM
SE DECISION MADE: 16-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ENDIUS INC.
ATTN: SUSAN FINNERAN
23 WEST BACON ST.
PLAINVILLE, MA 02762

510(k) NO: K002437
PHONE NO : 508-643-0983

DEVICE: ENDIUS ENDOSCOPIC ACCESS SYSTEM
SE DECISION MADE: 02-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ENDOCARE, INC.
ATTN: VINCENT CUTARELLI
7 STUDEBAKER
IRVINE, CA 92618

510(k) NO: K002396
PHONE NO : 949-595-5424

DEVICE: ENDOCARE PERCUTANEOUS ACCESS SET
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ENTIFIC MEDICAL SYSTEMS INC.
ATTN: CONSTANCE G BUNDY
6470 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432

510(k) NO: K002913
PHONE NO : 612-571-1976

DEVICE: HEADBAND FOR RAHA
SE DECISION MADE: 17-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ENVISION ADVANCED MEDICAL SYSTEM L510(k) NO: K002431
ATTN: GERARD J PRUD'HOMME
555 THIRTEENH STREET, N.W.
WASHINGTON, DC 20004-1109

PHONE NO : 202-637-5735

DEVICE: ELRAN 01 SYSTEM
SE DECISION MADE: 24-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

EUPALAMUS, LLC
ATTN: ANNE LAURITZEN
3411 MANDEVILLE CANYON ROAD
BRENTWOOD, CA 90049

510(k) NO: K002534
PHONE NO : 310-471-6289

DEVICE: EUPALAMUS DEFLECTABLE STYLET, MODEL 01545
SE DECISION MADE: 18-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

EVEREST MEDICAL CORP.
ATTN: DAVID KAY
FORTIRAN ROAD,
ST. MELLONS, CARDIFF,

510(k) NO: K003060
PHONE NO : 44 029 20776300

DEVICE: PLASMAKINETIC GENERATOR
SE DECISION MADE: 31-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

EXCEL TECH. LTD.
ATTN: DEBBIE DAVY
2568 BRISTOL CIRCLE
OAKVILLE, ONTARIO,

510(k) NO: K002332
PHONE NO : 905 829 5300

DEVICE: EEG SPIKE AND EVENT DETECTOR MODULE
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

FLEXIBLE DIMENSIONS LLC
ATTN: CAROL PATTERSON
21911 ERIE LANE
LAKE FOREST, CA 92630

510(k) NO: K001884
PHONE NO : 949-462-0900

DEVICE: DIRECT CROWN
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

FLUCRO SCAN IMAGING SYSTEMS, INC. 510(k) NO: K002198
MODEL TCA 4R PLUS
ATTN: WILLIAM J ENGEL
650-B ANTHONY TRAIL
NORTHBROOK, IL 60062

PHONE NO : 847-564-5400

DEVICE: FLUCROSCAN PROFILE, MODEL TCA 4 PLUS; FLUCROSCAN PROFILE IQ, M
SE DECISION MADE: 17-OCT-2000
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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CONAR CORP.
ATTN: LUCIANO BONANNI
110 MARCUS DR
MELVILLE, NY 11747

510(k) NO: K002490
PHONE NO : 631-694-2929

DEVICE: INCOMITABLE MAGNETIC RESONANCE IMAGING SCANNER
SE DECISION MADE: 03-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GALIL MEDICAL LTD.
ATTN: JONATHAN S KAHAN
555 THIRTEEN ST.
WASHINGTON, DC 20004

510(k) NO: K003065
PHONE NO : 202-637-5794

DEVICE: SEEDNET, MODEL EP6T5, EP5E5
SE DECISION MADE: 31-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GAMBRO HEALTHCARE
ATTN: JEFFREY R SHIDEMAN
1185 OAK ST.
LAKEWOOD, CO 80215

510(k) NO: K994390
PHONE NO : 612-835-4018

DEVICE: GAMBRO POLYFLUX 17R, CAPILLARY DIALYZER/ FILTER
SE DECISION MADE: 26-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GE MARQUETTE MEDICAL SYSTEMS, INC.
ATTN: DAVID WAHLIG
8200 WEST TOWER AVE.
MILWAUKEE, WI 53223

510(k) NO: K002957
PHONE NO : 414-362-2090

DEVICE: SOLAR SPO2 MODULE WITH MASIMO SET
SE DECISION MADE: 18-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GE MEDICAL SYSTEM /
ATTN: LARRY A KROGER
16800 RYERSON ROAD
NEW BERLIN, WI 53151

510(k) NO: K002978
PHONE NO : 262-544-3894

DEVICE: LIGHTSPEED 3.0 CT SCANNER SYSTEM
SE DECISION MADE: 10-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GE MEDICAL SYSTEMS
ATTN: LARRY A KROGER
P.O. BOX 414, W-709
MILWAUKEE, WI 53201

510(k) NO: K002611
PHONE NO : 262-544-3894

DEVICE: SIGNA MFO/I MAGNETIC RESONANCE SYSTEM
SE DECISION MADE: 31-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GEIGER MEDICAL TECHNOLOGIES, INC.
ATTN: JOHN BOTTJER
24040 CAMINO DEL AVION, A-195
MONARCH BEACH, CA 92629

510(k) NO: K002341
PHONE NO : 949-240-7584

DEVICE: THERMAL CAUTERY UNIT, MODEL 150
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GENICON, LC
ATTN: GARY HABERLAND
573 WATERSCAPE WAY
ORLANDO, FL 32828

510(k) NO: K002542
PHONE NO : 407-273-7619

DEVICE: REUSABLE CANNULA
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GEUDER GMEH
ATTN: HILLARD W WELCH
344 ANNAELLE POINT ROAD
CENTERVILLE, MA 02632-2402

510(k) NO: K001125
PHONE NO : 508-771-6777

DEVICE: GEUDER INJECTOR FOR MORCHER CAPSULAR TENSION RING
SE DECISION MADE: 04-OCT-2000
510(k) STATEMENT

GILLETTE CHILDREN'S SPECIALTY HEALTHCARE
ATTN: LINDA VALERI
1785 GOLD COURT
EAGAN, MN 55122

510(k) NO: K000861
PHONE NO : 651-229-3808

DEVICE: CRANIOCAP
SE DECISION MADE: 30-OCT-2000
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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GREINER VACUETTE NORTH AMERICA, IN510(k) NO: K002777
ATTN: JUDI SMITH PHONE NO : 410-313-8003
P.O. BOX 6581
ELLIOTT CITY, MD 21042-0581

DEVICE: VACUETTE WITH PPACK
SE DECISION MADE: 05-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GUIDANT CARDIAC AND VASCULAR SURGE510(k) NO: K002676
ATTN: KRISTEN HONL PHONE NO : 650-470-6200
1525 O'BRIEN DR.
MENLO PARK, CA 94025

DEVICE: ENDOVANCE DUALPASS TEAR-AWAY SHEATH INTRODUCER
SE DECISION MADE: 30-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

GUIDANT CORP. 510(k) NO: K002143
ATTN: SUSAN SILAVIN, PH.D. PHONE NO : 408-845-3127
3200 LAKESIDE DR.
SANTA CLARA, CA 95054

DEVICE: DYNALINK BILIARY SELF-EXPANDING STENT SYSTEM
SE DECISION MADE: 12-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

H&C MEDICAL DEVICES SPA 510(k) NO: K002074
W HES PHONE NO : 046-385-0125
ATTN: ATTILIO CASTELLI
VIA PISA 250
20099 SESTO SAN GIOVANNI
MILAN,

DEVICE: AB CARDIETTE DAEDALUS VIEW BASE AND AB CARDIETTE DAEDALUS VIEW
SE DECISION MADE: 04-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

HARALD NORDIN S.A 510(k) NO: K003219
ATTN: JAMES DELANEY PHONE NO : 978-371-0066
100 MAIN STREET; SUITE 120
CONCORD, MA 01742

DEVICE: HARALD NORDIN CARBONITE CARBON FIBER COMPOSITE DENTAL POST
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

HARALD NORDIN S.A 510(k) NO: K003221
ATTN: JAMES DELANEY PHONE NO : 978-371-0066
100 MAIN STREET; SUITE 120
CONCORD, MA 01742

DEVICE: HARALD NORDIN GLASSIX GLASS FIBER COMPOSITE DENTAL POST
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

HARDY DIAGNOSTICS 510(k) NO: K002367
ATTN: MELISSA M TRAYLOR PHONE NO : 805-346-2766
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

DEVICE: HARDY DISK CEFTIZOXIME, 30MCG
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

HARDY DIAGNOSTICS 510(k) NO: K002368
ATTN: MELISSA M TRAYLOR PHONE NO : 805-346-2766
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

DEVICE: HARDYDISK STREPTOMYCIN, 300MCG
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

HARDY DIAGNOSTICS 510(k) NO: K002369
ATTN: MELISSA M TRAYLOR PHONE NO : 805-346-2766
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

DEVICE: HARDYDISK GENTAMICIN, 120MCG
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

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HARDY DIAGNOSTICS
ATTN: MELISSA M TRAYLOR
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

510(k) NO: K002656
PHONE NO : 805-346-2766

DEVICE: HARDYDISK CEFUROXIME, 30MCG
SE DECISION MADE: 25-OCT-2000
510(k) STATEMENT

HARDY DIAGNOSTICS
ATTN: MELISSA M TRAYLOR
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

510(k) NO: K002660
PHONE NO : 805-346-2766

DEVICE: HARDYDISK LOMEFLOXACIN, 10MCG
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

HARDY DIAGNOSTICS
ATTN: MELISSA M TRAYLOR
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

510(k) NO: K002661
PHONE NO : 805-346-2766

DEVICE: HARDYDISK CEFODETAN, 30MCG
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

HARDY DIAGNOSTICS
ATTN: MELISSA M TRAYLOR
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

510(k) NO: K002663
PHONE NO : 805-346-2766

DEVICE: HARDYDISK NETILMICIN, 30MCG
SE DECISION MADE: 19-OCT-2000
510(k) STATEMENT

HARDY DIAGNOSTICS
ATTN: MELISSA M TRAYLOR
1430 WEST MCCOY LANE
SANTA MARIA, CA 93455

510(k) NO: K002664
PHONE NO : 805-346-2766

DEVICE: HARDYDISK LEVOFLOXACIN, 5MCG
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

HDC CORP.
51-07
ATTN: JAMES ABILLA
2109 O'TOOLE AVE.
SAN JOSE, CA 95131

510(k) NO: K994059
PHONE NO : 408-954-1909

DEVICE: CLA KIT (CONTINUOUS LOCAL ANESTHESIA), MODEL 551-17, 551-10, 5
SE DECISION MADE: 13-OCT-2000
510(k) STATEMENT

HEALTH & LIFE CO., LTD.
ATTN: PAUL YANG
6F,NO. 407, CHUNG SHAN RD.
SEC.02, CHUNG HO CITY
TAIPEI HSIEN,

510(k) NO: K002882
PHONE NO : 886 2 32349600

DEVICE: HL168B
SE DECISION MADE: 13-OCT-2000
510(k) STATEMENT

HEMAGEN DIAGNOSTICS, INC.
ATTN: JOSE A MONTANEZ
9033 RED BRANCH ROAD
COLUMBIA, MD 21045-2105

510(k) NO: K003012
PHONE NO : 443-367-5518

DEVICE: RAICHEM PHOSPORUS REAGENT
SE DECISION MADE: 25-OCT-2000
510(k) STATEMENT

HEYER AMERICA, INC.
ATTN: ART WARD
3234 ELLA LANE
NEW PORT RICHEY, FL 34655

510(k) NO: K000995
PHONE NO : 813-645-2855

DEVICE: NARKOMAT, MODEL 2000
SE DECISION MADE: 11-OCT-2000
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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HITACHI MEDICAL SYSTEMS AMERICA, ATTN: DOUGLAS THISLEITHWAITE 1959 SUMMIT COMMERCE PARK TWINSBURG, OH 44087-2371	510(k) NO: K002420 PHONE NO : 330-425-1313	DEVICE: HITACHI ALTAIRE SE DECISION MADE: 17-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
HOSUK CO., LTD. ATTN: Y. H KIM 52-6 DUKJECNG-RI, SAMSUNG-MYUN UMSUNG-GUN, CHUNGCHONG,	510(k) NO: K002921 PHONE NO : 011 82 438830411	DEVICE: SUREONE INSULIN SYRINGE SE DECISION MADE: 18-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: MARY-CAATHERINE DILLON 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K002505 PHONE NO : 201-760-8117	DEVICE: XIA SPINE SYSTEM SE DECISION MADE: 05-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: MARY-CAATHERINE DILLON 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K002858 PHONE NO : 201-760-8117	DEVICE: XIA SPINE SYSTEM SE DECISION MADE: 13-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
HUNTER RESEARCH LABORATORIES, INC. ATTN: BARBARA PEDIGO 1541 SOUTH VINE ST. DENVER, CO 80210	510(k) NO: K002213 PHONE NO : 303-744-1989	DEVICE: BULL'S-EYE DISPOSABLE NEEDLE RECAPPING AID SE DECISION MADE: 03-OCT-2000 510(k) STATEMENT
I-STAT CORP. ATTN: PAUL VANDERWERF 104 WINDSOR CENTER DR. EAST WINDSOR, NJ 08520	510(k) NO: K001387 PHONE NO : 609-469-0242	DEVICE: I-STAT PORTABLE CLINICAL ANALYZER, MODEL 300 SE DECISION MADE: 05-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
IC-USA, INC. ATTN: CAROL PATTERSON 21911 ERIE LANE LAKE FOREST, CA 92630	510(k) NO: K001972 PHONE NO : 949-462-0900	DEVICE: ARGUS SYSTEM-CONTINUOUS EXPERT CARE NETWORK SE DECISION MADE: 27-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
IMAGE-GUIDED NEUROLOGICS, INC. ATTN: DAVID M LEE 2290 EAU GALLIE BLVD. MELBOURNE, FL 32935	510(k) NO: K001096 PHONE NO : 321-757-8990	DEVICE: BURR HOLE COVER, MODEL XX SE DECISION MADE: 25-OCT-2000 510(k) STATEMENT
IMAGE-GUIDED NEUROLOGICS, INC. ATTN: DAVID M LEE 2290 EAU GALLIE BLVD. MELBOURNE, FL 32935	510(k) NO: K002330 PHONE NO : 321-757-8990	DEVICE: NAVIGUS PEEL AWAY INTRODUCER SE DECISION MADE: 18-OCT-2000 510(k) STATEMENT
IMPLANT RESOURCE, INC. ATTN: AL LIPPINCOTT 3150 E. 200TH STREET PRIOR LAKE, MN 55372	510(k) NO: K002125 PHONE NO : 952-492-5858	DEVICE: PINS AND WIRES SE DECISION MADE: 11-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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IMPOAID, INC.
ATTN: ELAIN DUNCAN
P.O. BOX 560
STILLWATER, MN 55082

510(k) NO: K000730
PHONE NO : 715-549-6035

DEVICE: IMPOAID
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

INSIGHT INSTRUMENTS MFG., INC.
ATTN: K. PETER LULOH
5400 SOUTH BRYANT AVE.
SANFORD, FL 32773

510(k) NO: K000252
PHONE NO : 407-324-2727

DEVICE: INSIGHT 4000 ENDOSCOPE
SE DECISION MADE: 17-OCT-2000
510(k) STATEMENT

INSTRUMENTATION LABORATORY CO.
ATTN: CAROL MARBLE
113 HARIWELL AVE.
LEXINGTON, MA 02421

510(k) NO: K002467
PHONE NO : 781-861-4467

DEVICE: COALIZA PROTEIN S-FREE
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

INTERPORE CROSS INVL.
ATTN: PROSIE REY-FESSLER
181 TECHNOLOGY DR.
IRVINE, CA 92618-2402

510(k) NO: K002592
PHONE NO : 949-453-3200

DEVICE: INTERPORE CROSS ANTERIOR CERVICAL PLATE SYSTEM
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

INVACARE CORP.
ATTN: EDWARD A KROLL
ONE INVACARE WAY
ELYRIA, OH 44036-2125

510(k) NO: K002284
PHONE NO : 440-329-6595

DEVICE: VENIURE IDD OXYGEN CONSERVING DEVICE IDD 20EX AND 50EX
SE DECISION MADE: 24-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

IOMED, INC.
ATTN: W. TIM MILLER
3385 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104

510(k) NO: K001522
PHONE NO : 801-975-1191

DEVICE: TRANSQ3
SE DECISION MADE: 18-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K002645
PHONE NO : 914-273-8600

DEVICE: JEL BIOS PURE
SE DECISION MADE: 19-OCT-2000
510(k) STATEMENT

JENSEN INDUSTRIES, INC.
ATTN: JOHN SLANSKI
50 STILLMAN RD.
NORTH HAVEN, CT 06473

510(k) NO: K002826
PHONE NO : 203-239-2090

DEVICE: EQUITY
SE DECISION MADE: 24-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

JIANGSU INTCO MEDICAL EQUIPMENT &
ATTN: JAMES CHU
12390 EAST END AVENUE
CHINO, CA 91710

510(k) NO: K002669
PHONE NO : 909-548-4828

DEVICE: EZ-LIGHT 4000 SERIES MANUAL WHEELCHAIR
SE DECISION MADE: 11-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

JIANGSU INTCO MEDICAL EQUIPMENT &
ATTN: JAMES CHU
12390 EAST END AVENUE
CHINO, CA 91710

510(k) NO: K002670
PHONE NO : 909-548-4828

DEVICE: EZ-TRAVELER 3000 SERIES MANUAL WHEELCHAIR
SE DECISION MADE: 11-OCT-2000
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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JIANGSU INTCO MEDICAL EQUIPMENT & 510(k) NO: K002671
ATTN: JAMES CHU PHONE NO : 909-548-4828
12390 EAST END AVENUE
CHINO, CA 91710

DEVICE: EZ-TRAVELER 2500 SERIES MANUAL WHEELCHAIR
SE DECISION MADE: 11-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

JIANGSU INTCO MEDICAL EQUIPMENT & 510(k) NO: K002673
ATTN: JAMES CHU PHONE NO : 909-548-4828
12390 EAST END AVENUE
CHINO, CA 91710

DEVICE: EZ-COMFORT TRANSPORTER 2000 SERIES
SE DECISION MADE: 11-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

JOSIRA AG 510(k) NO: K002857
ATTN: KATHLEEN JOHNSON PHONE NO : 302-454-9959
2035 SUNSET LAKE ROAD
NEWARK, DE 19702

DEVICE: ELS CANNULA (KIT), MODEL M1210-88,M1510-88
SE DECISION MADE: 05-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

KAMIYA BIOMEDICAL CO. 510(k) NO: K002558
ATTN: COLIN GEMTY PHONE NO : 206-575-8068
910 INDUSTRY DR.
SEATTLE, WA 98188-3412

DEVICE: K-ASSAY HIGH SENSITIVE CRP(2) FOR THE BECKMAN COULTER IMAGE
SE DECISION MADE: 25-OCT-2000
510(k) STATEMENT

KARL STORZ ENDOSCOPY-AMERICA, INC. 510(k) NO: K001408
ATTN: KEVIN KENNAN PHONE NO : 310-410-2769
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600

DEVICE: KSEA VASCULAR FIBERSCOPIES
SE DECISION MADE: 30-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

KARL STORZ ENDOSCOPY-AMERICA, INC. 510(k) NO: K002700
ATTN: KEVIN KENNAN PHONE NO : 310-410-2769
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600

DEVICE: KSEA UNIMAT 12
SE DECISION MADE: 18-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

KARL STORZ ENDOSCOPY-AMERICA, INC. 510(k) NO: K002788
ATTN: KEVIN KENNAN PHONE NO : 310-410-2769
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600

DEVICE: KSEA NEURO-FIBERSCOPE
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

KLS-MARTIN L.P. 510(k) NO: K002152
LUS DISTRACTION
ATTN: ART WARD PHONE NO : 813-645-2855
3234 ELLA LANE
NEW PORT RICHEY, FL 34655

DEVICE: TRACK 1.0 & 1.5 MM SYSTEMS-TISSUE REGENERATION BY ALVEOLAR CAL
SE DECISION MADE: 10-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

LAERDAL MEDICAL CORP. 510(k) NO: K001742
ATTN: CYNTHIA J NOLTE PHONE NO : 919-859-4207
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760

DEVICE: RESUSCI INFLATE-A-SHIELD CPR BARRIER
SE DECISION MADE: 06-OCT-2000
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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LIGHT FORCE THERAPY, INC.
ATTN: KIM PETERSON
17725 CLEESE CT.
PAYTON, CO 80831

510(k) NO: K001179
PHONE NO : 719-749-2974

DEVICE: SUPER NOVA, ACUBEAM
SE DECISION MADE: 27-OCT-2000
510(k) STATEMENT

LINVATEC CORP.
ATTN: LAURA D SENEFF
11311 CONCEPT BOULEVARD
LARGO, FL 33773-4908

510(k) NO: K002523
PHONE NO : 727-399-5234

DEVICE: ADVANTAGE DRIVE SYSTEM
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

LUMALITE, INC.
ATTN: JOSEPH M FOREHAND
2810 VIA ORANGE WAY, STE. B
SPRING VALLEY, CA 91978

510(k) NO: K002566
PHONE NO : 619-660-5410

DEVICE: LUMALITE CURE LIGHT, MODEL 2100
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MACROPORE, INC.
ATTN: KENNETH K KLEINHENZ
6740 TOP GUN ST.
SAN DIEGO, CA 92121

510(k) NO: K000696
PHONE NO : 858-458-0900

DEVICE: MACROPOREMX MANDIBULAR FIXATION SYSTEM
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MADA MEDICAL PRODUCTS, INC.
ATTN: JEFFERY W ADAM
625 WASHINGTON AVE
CARLSTADT, NJ 07072

510(k) NO: K002943
PHONE NO : 201-460-0454

DEVICE: WHEELCHAIR, MECHANICAL SERIES MODEL 3100
SE DECISION MADE: 23-OCT-2000
510(k) STATEMENT

MAP MEDIZINTECHNIK FUR ARZT UND PA
ATTN: TORSTEN SCHLICHHOLZ
FRAUNHOFERSTRASSE 16
MUNCHEN,

510(k) NO: K993094
PHONE NO : 498 989 518723

DEVICE: AERO-CLICK
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MARQUETTE HELDIGE GMBH
ATTN: KLAUS RUDOLF
MINZINGER STR. 3
D-79111 FREIBURG,

510(k) NO: K000638
PHONE NO : 761-454-3379

DEVICE: RESPONDER 3000
SE DECISION MADE: 30-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MARYROSE CUSIMANO, PH.D. & SCOTT Z
ATTN: MARYROSE CUSIMANO
7481 W. OAKLAND PARK BLVD.
305
FT. LAUDERDALE, FL 33319

510(k) NO: K002104
PHONE NO : 954-578-6884

DEVICE: COMBINED PHYSIOLOGICAL MONITORING SYSTEM
SE DECISION MADE: 10-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MASIMO CORP.
S OF SENSORS AND CABLES
ATTN: JAMES J CRONIN
2852 KELVIN AVE.
IRVINE, CA 92614-5826

510(k) NO: K002751
PHONE NO : 949-250-9688

DEVICE: MASIMO SET RADICAL PULSE OXIMETER WITH SATSHARE AND LNOP SERIE
SE DECISION MADE: 05-OCT-2000
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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MASIMO CORP. E AND LNOF SERIES OF SENSORS OXIMETER ATTN: JAMES J CRONIN 2852 KELVIN AVE. IRVINE, CA 92614-5826	510(k) NO: K002939 PHONE NO : 949-250-9688	DEVICE: MODIFICATION TO MASIMO SET RADICAL PULSE OXIMETER WITH SATSHAR SE DECISION MADE: 06-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MAXXIM MEDICAL GLOVES ATTN: PALLIE STODDARD 308 CHURCH STREET HONE PATH, SC 29654	510(k) NO: K002933 PHONE NO : 864-369-7391	DEVICE: STERILE SENSICARE SYNTHETIC POLYISOPRENE POWDER-FREE SURGICAL SE DECISION MADE: 19-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL BIO CARE SWEDEN AB ATTN: CONNIE WHITE HOY 9630 TOWNER NE ALBUQUERQUE, NM 87112	510(k) NO: K000929 PHONE NO : 505-323-2403	DEVICE: PROLITE PULSED LIGHT SYSTEM SE DECISION MADE: 17-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL DEVICE TECHNOLOGIES, INC. ATTN: KARL SWARTZ 3600 S.W. 47TH AVE. GAINESVILLE, FL 32608	510(k) NO: K000620 PHONE NO : 352-338-0440	DEVICE: PEN FALLOPIAN TUBE CATHETER SYSTEM SE DECISION MADE: 30-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDINOL LTD. ATTN: NASR SALMAN KIRYAT ATIDIM, P.O.B. 58165 TEL-AVIV,	510(k) NO: K002130 PHONE NO : 972 648 1448	DEVICE: NIR BILIARY STENT SE DECISION MADE: 30-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDISON AMERICA, INC. ATTN: GARY J ALLSEBROCK 16303 PANORAMIC WAY SAN LEANDRO, CA 94578-1116	510(k) NO: K003121 PHONE NO : 510-276-3559	DEVICE: MYSONO 201 DIAGNOSTIC ULTRASOUND AND TRANSDUCERS SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDISYSTEMS CORP. ATTN: FREDRIC SWINDLER 1201 3RD AVE. SEATTLE, WA 98101-3016	510(k) NO: K002372 PHONE NO : 206-621-6500	DEVICE: ACCESS ALERT GAUGE SE DECISION MADE: 25-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDIVANCE, INC. IT AND PATIENT ENERGY TRANSFER PADS ATTN: ROBERT A KLINE 500 S. ARTHUR AVENUE, STE 100 LOUISVILLE, CO 80027	510(k) NO: K002577 PHONE NO : 303-926-1917	DEVICE: ARCTIC SUN TEMPERATURE MANAGEMENT SYSTEM, MODEL 100 CONTROL UN SE DECISION MADE: 26-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDLINE INDUSTRIES, INC. ATTN: LARA N SIMMONS ONE MEDLINE PL. MUNDELEIN, IL 60060-4486	510(k) NO: K003091 PHONE NO : 847-949-2639	DEVICE: MEDLINE STERILE VINYL EXAM GLOVES, POWDER FREE, YELLOW SE DECISION MADE: 24-OCT-2000 510(k) STATEMENT

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MENICON CO. LTD.
ATTN: BEVERLEY D VENUTI
269A BALLARDVALE STREET
WILMINGTON, MA 01887

510(k) NO: K002140
PHONE NO : 978-658-6888

DEVICE: MENICON PROGENT REMOVER
SE DECISION MADE: 10-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MERIDIAN MEDICAL TECHNOLOGIES LTD.
ATTN: GERARD LYNN
207 AIRPORT RD., WEST
BELFAST,

510(k) NO: K002310
PHONE NO : 442 890 222333

DEVICE: CARDIOKEEPER CB12/12, MODEL CB12/12
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MERIT MEDICAL SYSTEMS, INC.
ATTN: CHESTER MCCOY
1600 WEST MERIT PKWY.
SOUTH JORDAN, UT 84095

510(k) NO: K002289
PHONE NO : 801-208-4404

DEVICE: INOWIRE DIAGNOSTIC GUIDE WIRE
SE DECISION MADE: 04-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MICRO DETECT, INC.
ATTN: MEHDI ALEM
2852 WALNUT AVE., SUITE H-1
TUSTIN, CA 92780-7033

510(k) NO: K002358
PHONE NO : 714-832-8234

DEVICE: MDI GLIADIN A TEST
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MICRO DETECT, INC.
ATTN: MEHDI ALEM
2852 WALNUT AVE., SUITE H-1
TUSTIN, CA 92780-7033

510(k) NO: K002359
PHONE NO : 714-832-8234

DEVICE: MDI GLIADIN G TEST
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MIDMARK CORP.
ATTN: MIKE SNYDER
CUTE 47 WEST, VISTA DRIVE
VERSAILLES, OH 45380

510(k) NO: K003090
PHONE NO : 937-526-8390

DEVICE: MIDMARK PROCENTER INSTRUMENT DELIVERY SYSTEM
SE DECISION MADE: 18-OCT-2000
510(k) STATEMENT

MISONIX, INC.
ATTN: ALBERT F CLANCY JR.
1938 NEW HIGHWAY
FARMINGDALE, NY 11735

510(k) NO: K000927
PHONE NO : 516-694-9555

DEVICE: ALLIGER ULTRASONIC SURGICAL SYSTEM MODEL AUSS-4
SE DECISION MADE: 10-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MITEK PRODUCTS
ATTN: CHRISTINE KUNTZ-NASSIF
249 VANDERBILT AVE.
NORWOOD, MA 02062

510(k) NO: K003076
PHONE NO : 781-251-2794

DEVICE: MITEK CUFFTACK
SE DECISION MADE: 27-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

MORIA S.A.
ATTN: DAVID CONRAD
15 RUE GEORGES BESSE
ANTONY,

510(k) NO: K002191
PHONE NO : 331 467 44674

DEVICE: CARRIAZO BARRAQUER II MICROKERATOME
SE DECISION MADE: 12-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

NARISHIGE CO., LTD.
ATTN: MITSUKO YONEYAMA
27-9 MINAMIKARASUYAMA 4-CHOME
SETAGAY-KU, TOKYO 157-0062,

510(k) NO: K002850
PHONE NO : 813 330 88383

DEVICE: MWO-202 3D HYDRAULIC COARSE/FINE MICROMANIPULATOR
SE DECISION MADE: 05-OCT-2000
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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NELCOR PURITAN BENNETT, INC. CHIEVA PSO2 VENTILATOR Y-ACHPS02+E ATTN: CHERYL NORTON 2800 NORTHWEST BLVD. MINNEAPOLIS, MN 55441	510(k) NO: K002686 PHONE NO : 763-694-3500	DEVICE: ACHIEVA VENTILATOR Y-ACH+E, ACHIEVA PS VENTILATOR Y-ACHPS+E, A SE DECISION MADE: 18-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NEU-ION, INC. ATTN: LEE A HEIKKINEN 7200 RUTHERFORD RD. SUITE 100 BALTIMORE, MD 21244-2704	510(k) NO: K001811 PHONE NO : 410-944-5200	DEVICE: NEU-ION HEMODIALYSIS WATER TREATMENT SYSTEM SE DECISION MADE: 25-OCT-2000 510(k) STATEMENT
NICHOLS INSTITUTE DIAGNOSTICS ATTN: JIMMY WONG 33047 CALLE AVIADOR SAN JUAN CAPISTRANO, CA 92675	510(k) NO: K002888 PHONE NO : 949-240-5260	DEVICE: NICHOLS ADVANTAGE THYROGLOB SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NIHON KOHDEN AMERICA, INC. ATTN: BONNIE BISHOP 2601 CAMPUS DR. IRVINE, CA 92612-1601	510(k) NO: K001693 PHONE NO : 949-250-3210	DEVICE: LIFE SCOPE P, MODEL BSM-4100 SERIES SE DECISION MADE: 24-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NONIN MEDICAL, INC. ATTN: RICHARD P BENNETT 2605 FERNERCOCK LANE, NORTH MINNEAPOLIS, MN 55447-4755	510(k) NO: K002690 PHONE NO : 612-553-9968	DEVICE: MODEL 2500, PALMSAT HAND HELD PULSE OXIMETER, MODEL 2500 SE DECISION MADE: 11-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NORDISKA DENTAL AB ATTN: RICHARD KIRSCHNER P.O. BOX 435 LYNWOOD, WA 98046	510(k) NO: K002808 PHONE NO : 425-745-2584	DEVICE: ANA 2000 NON GAMMA 2 EXTRA HIGH COPPER DENTAL ALLOY SE DECISION MADE: 31-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NORDISKA DENTAL AB ATTN: RICHARD KIRSCHNER P.O. BOX 435 LYNWOOD, WA 98046	510(k) NO: K002810 PHONE NO : 425-745-2584	DEVICE: ANA 3000 SM NON GAMMA 2 MODIFIED SPHERICAL DENTAL ALLOY SE DECISION MADE: 31-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NORDISKA DENTAL AB ATTN: RICHARD KIRSCHNER P.O. BOX 435 LYNWOOD, WA 98046	510(k) NO: K002811 PHONE NO : 425-745-2584	DEVICE: ANA 70 NON GAMMA 2 DISPERSED PHASE DENTAL ALLOY SE DECISION MADE: 31-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
NOVA BIOMEDICAL CORP. ATTN: PAUL W MACDONALD 200 PROSPECT ST. WALTHAM, MA 02254-9141	510(k) NO: K002613 PHONE NO : 781-894-0800	DEVICE: MODIFICATION TO STAT PROFILE PHOX PLUS ANALYZER SE DECISION MADE: 19-OCT-2000 510(k) STATEMENT

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OASIS ATTN: YVONNE FERNANDEZ 514 SOUTH VERMONT AVENUE GLENDCRA, CA 91741	510(k) NO: K001464 PHONE NO : 626-914-2891	DEVICE: DISPOSABLE H-PE MICROKERATOME BLADES SE DECISION MADE: 02-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
OASIS RESEARCH, LLC ATTN: JAMES CHRISTENSEN 514 S. VERMONT AVENUE GLENDCRA, CA 91741	510(k) NO: K002443 PHONE NO : 909-305-9857	DEVICE: COLLAGEN WOUND DRESSING SE DECISION MADE: 18-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
ODC OPHTHALMIC DEVELOPMENT CO. AG ATTN: KEVIN WALLS 777 S. WADSWORTH BLVD. BLDG. 2, SUITE 102 LAKEWOOD, CO 80226	510(k) NO: K002510 PHONE NO : 720-962-5412	DEVICE: SMARTLENS SE DECISION MADE: 18-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
OLYMPUS AMERICA, INC. ATTN: MICHAEL CAMPBELL 3131 WEST ROYAL LANE IRVING, TX 75063-3104	510(k) NO: K002918 PHONE NO : 972-556-9697	DEVICE: OLYMPUS CRP LATEX IMMUNOTURBIDIMETRIC REAGENT SE DECISION MADE: 25-OCT-2000 510(k) STATEMENT
OLYMPUS AMERICA, INC. ATTN: MICHAEL CAMPBELL 3131 WEST ROYAL LANE IRVING, TX 75063-3104	510(k) NO: K002982 PHONE NO : 972-556-9697	DEVICE: OLYMPUS AU2700 CLINICAL CHEMISTRY ANALYZER SE DECISION MADE: 25-OCT-2000 510(k) STATEMENT
OMNIGRACE (THAILAND) LTD. IM (200 MICROGRAMS OR LESS) ATTN: WILLIAM E PATTON 7815 VANDERBILT DRIVE NW NORTH CANTON, OH 44720	510(k) NO: K002922 PHONE NO : 330-966-8878	DEVICE: OMNI GRACE LATEX EXAMINATION GLOVE, POWDERED, WITH PROTEIN CLA SE DECISION MADE: 16-OCT-2000 510(k) STATEMENT
ORASYSTEMS, LLC ATTN: BERNARD SESSMAN 555 PASSAIC AVENUE WEST CALDWELL, NJ 07006	510(k) NO: K000848 PHONE NO : 973-227-5505	DEVICE: TDK HANDPIECES SE DECISION MADE: 05-OCT-2000 510(k) STATEMENT
ORGANON TEKNIKA CORP. ATTN: REBECCA A RIVAS 100 AKZO AVE. DURHAM, NC 27712	510(k) NO: K003104 PHONE NO : 919-620-2288	DEVICE: BACT/ALERT CSR SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
OTTO BOCK ORTHOPEDIC INDUSTRY, INC ATTN: WILLIAM JACKSON 3000 XENIUM LANE, SUITE N PLYMOUTH, MN 55441	510(k) NO: K000739 PHONE NO : 615-773-0002	DEVICE: EVANIGARDE/ENDEAVOR POWERED WHEELCHAIR SE DECISION MADE: 24-OCT-2000 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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OXFORD BIOSIGNALS LIMITED ATTN: PAULINE A HOEDAY OXFORD SCIENCE PARK OXFORD, OX4 4 GA,	510(k) NO: K002622 PHONE NO : 440 186 5784840	DEVICE: BIOSLEEP SE DECISION MADE: 23-OCT-2000 510(k) STATEMENT
P.T. HEALTHCARE GLOVINDO CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS) ATTN: ELLEN HUTAPEA JL. KOL. YOS SUDARSO K.M. 10 KAWASAN INDUSRI MEDAN MEDAN,	510(k) NO: K000838 PHONE NO : 62 61 650015	DEVICE: DIGITICARE POWDER FREE COATED EXAMINATION GLOVES WITH PROTEIN C SE DECISION MADE: 23-OCT-2000 510(k) STATEMENT
PACE MEDICAL A, 5265V ATTN: ROBERT C MACE 391 TOTTEN POND RD. WALIHAM, MA 02451	510(k) NO: K002204 PHONE NO : 781-890-5656	DEVICE: PACEMAKER EXTENSION CABLE MODELS 4265,4265A, 4265V, 5265, 5265 SE DECISION MADE: 18-OCT-2000 510(k) STATEMENT
PACE MEDICAL ATTN: ROBERT C MACE 391 TOTTEN POND RD. WALIHAM, MA 02451	510(k) NO: K002496 PHONE NO : 781-890-5656	DEVICE: MODEL 4815 ADAPTER SE DECISION MADE: 10-OCT-2000 510(k) STATEMENT
PACE MEDICAL ATTN: ROBERT C MACE 391 TOTTEN POND RD. WALIHAM, MA 02451	510(k) NO: K002497 PHONE NO : 781-890-5656	DEVICE: MODEL 4810 ANALYZER OUTPUT ADAPTER SE DECISION MADE: 10-OCT-2000 510(k) STATEMENT
PARADIGM MEDICAL INDUSTRIES, INC. 5-"X" ATTN: TRACY S BEST 2355 SOUTH 1070 WEST SALT LAKE CITY, UT 84119	510(k) NO: K002228 PHONE NO : 801-977-8970	DEVICE: PHOTON MODULAR WORKSTATION SYSTEM, MODELS Z-12834-"X" & Z-1317 SE DECISION MADE: 06-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
PEGASUS RESEARCH CORP. ATTN: E J SMITH 1714 SOUTH LYON ST. SANTA ANA, CA 92705	510(k) NO: K983783 PHONE NO : 410-451-0639	DEVICE: HEATED HUMIDIFIER SE DECISION MADE: 24-OCT-2000 510(k) STATEMENT
PERCLOSE, INC. ATTN: DENISE C SUNGLETON 400 SAGINAW DRIVE REDWOOD CITY, CA 94063	510(k) NO: K001703 PHONE NO : 650-474-3193	DEVICE: PERCLOSE VASCULAR SUTURE DELIVERY DEVICE SE DECISION MADE: 03-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
PFM PRODUKTE FUR DIE MEDIZIN AG ATTN: SALVADORE F PALOMARES 15 CHEROKEE STREET TRABUCCO CANYON, CA 92679	510(k) NO: K002471 PHONE NO : 949-463-6146	DEVICE: JETCAN HUBER NEEEDLE SET SE DECISION MADE: 19-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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PHARMACIA & UPJOHN CO.
ATTN: TONI D ELLIOTT
592 CERESIA COURT
PICKERINGTON,, OH 43147

510(k) NO: K002556
PHONE NO : 614-834-8629

DEVICE: CEBON EASYSERT INTRAOCULAR LENS INJECTOR, MODEL IMP-1
SE DECISION MADE: 31-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

PHOENIX BIOTECH CORP.
ATTN: GARY LEHNUS
53 CEDAR LAKE ROAD
BLAIRSTOWN, NJ 07825

510(k) NO: K001552
PHONE NO : 908-362-9288

DEVICE: TREPCEK TREPONEMAL ANTIBODY EIA
SE DECISION MADE: 19-OCT-2000
510(k) STATEMENT

PIE MEDICAL
ATTN: COLLEEN J HITTLE
INDIANAPOLIS, IN 46250

510(k) NO: K002880
PHONE NO : 317-849-1916

DEVICE: 300LC ULTRASOUND IMAGING SYSTEMS, MODEL 300LC
510(k) SUMMARY AVAILABLE FROM FDA

PIONEER LABORATORIES, INC.
ATTN: AMY H MCMAERTS
375 RIVER PARK CIRCLE
MARQUETTE, MI 49855-0627

510(k) NO: K002110
PHONE NO : 906-226-9909

DEVICE: SPL CRIMP SYSTEM
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILAABLE FROM FDA

PLUS ORTHOPEDICS
ATTN: HARIMUT LOCH
3550 GENERAL ATOMICS CT.
BLDG. 15-100
SAN DIEGO, CA 92121-1122

510(k) NO: K000666
PHONE NO : 858-455-2400

DEVICE: TC-PLUS SOLUTION KNEE
SE DECISION MADE: 13-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

POINTE SCIENTIFIC, INC.
ATTN: RON JAMISON
1025 JOHN A. PAPALAS DR.
LINCOLN PARK, MI 48146

510(k) NO: K002651
PHONE NO : 313-383-7220

DEVICE: C-REACTIVE PROTEIN (HIGH SENSITIVITY) REAGENT SET
SE DECISION MADE: 13-OCT-2000
510(k) STATEMENT

POLYMER TECHNOLOGY
ATTN: DEBRA L.B. KETCHUM
1400 N GOODMAN STREET
P.O. BOX 30450
ROCHESTER, NY 14603-0450

510(k) NO: K002025
PHONE NO : 716-338-8638

DEVICE: RIGID GAS PERMEABLE CONTACT LENS
SE DECISION MADE: 31-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

POLYSTAN A/S
ATTN: THOMAS ANDERSEN
WALGERHOLM 8
VAERLOSE,

510(k) NO: K980974
PHONE NO : 454-465-1566

DEVICE: SAFE MINI
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

PRODUCT DEVELOPMENT INDUSTRIES,
ATTN: RODOLFO A CARBALLO
4500 EAST SPEEDWAY BLVD., #50
TUCSON, AZ 85712

510(k) NO: K002675
PHONE NO : 520-881-2556

DEVICE: MILLENNIUM EDITION 2000 ACCELERATED ELECTROFORMING SYSTEM
SE DECISION MADE: 25-OCT-2000
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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FRONOSCO A/S
ATTN: JONATHAN KAHAN
555 13TH STREET
WASHINGTON, DC 20004

510(k) NO: K002500
PHONE NO : 202-637-5794

DEVICE: X-POSURE SYSTEM VERSION 2 RAD
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

PULMONETIC SYSTEMS, INC.
ATTN: ROBERT HANKINS
930 SOUTH MT. VERNON AVE.,
SUITE 100
COLTON, CA 92324-3928

510(k) NO: K002881
PHONE NO : 909-783-2280

DEVICE: VENTILATOR, CONTINUOUS (RESPIRATOR), MODEL LIV 1000
SE DECISION MADE: 11-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

PURITAN BENNETT CORP.
ATTN: MARY E FUNK
2200 FARADAY AVE.
CARLSBAD, CA 92008

510(k) NO: K001646
PHONE NO : 760-603-5957

DEVICE: PURITAN-BENNETT 840 VENTILATOR SYSTEM WITH NECMODE OPTION
SE DECISION MADE: 20-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

QUALIGEN, INC.
ATTN: DOROTHY DEINZER
2042 CORTE DEL NOGAL,
CARLSBAD, CA 92009-1410

510(k) NO: K003094
PHONE NO : 760-918-9165

DEVICE: FASTPACK PSA IMMUNOASSAY, FASTPACK ANALYZER
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

R.S. MCQUATE AND ASSOCIATES, INC.
ATTN: ROBERT S MCQUATE
3636 E. COLUMBINE DR.
PHOENIX, AZ 85032-7372

510(k) NO: K002983
PHONE NO : 602-788-5651

DEVICE: C.T.M. POWER CHAIR, MODEL HS-5600
SE DECISION MADE: 11-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

RADI MEDICAL SYSTEMS AB
ATTN: MATS GRANLUND
PALMBLADSGATAN 10
UPPSALA,

510(k) NO: K002962
PHONE NO : 461 816 1000

DEVICE: PRESSURE WIRE SENSOR, MODEL 12003/12303
SE DECISION MADE: 04-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

RADIOMED CORPORATION
ATTN: JOHN SCHWABE
9 LINNELL CIRCLE
BILLERICA, MA 01821

510(k) NO: K001070
PHONE NO : 978-663-7400

DEVICE: RADIOMED SOURCE
SE DECISION MADE: 24-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

RADIONICS, INC.
ATTN: KRISTINE CANAVAN
22 TERRY AVE.
BURLINGTON, MA 01803

510(k) NO: K001741
PHONE NO : 781-272-1233

DEVICE: RADIONICS RF DISC CATHETER ELECTRODE SYSTEM
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

RADIONICS, INC.
ATTN: NANCY C MACDONALD
22 TERRY AVE.
BURLINGTON, MA 01803

510(k) NO: K002773
PHONE NO : 781-272-1233

DEVICE: NEUROMAP WITH NEURO 100
SE DECISION MADE: 23-OCT-2000
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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RANDEX LABORATORIES LTD.
ATTN: PAULINE ARMSTRONG
55 DIAMOND RD.
CRUMLIN, CO. ANTRIM,

510(k) NO: K002674
PHONE NO : 441 849 422413

DEVICE: RANDEX MICROALBUMIN
SE DECISION MADE: 05-OCT-2000
510(k) STATEMENT

REPMEDIX CORP
ATTN: HAN-SOO KIM
86 CUMMINGS PARK,
WOBURN, MA 01801

510(k) NO: K001603
PHONE NO : 781-667-8893

DEVICE: REPROBEAD T4 ENZYME IMMUNOASSAY REAGENT KIT (CATALOG# 105)
SE DECISION MADE: 05-OCT-2000
510(k) STATEMENT

REPMEDIX CORP
ATTN: HAN-SOO KIM
86 CUMMINGS PARK,
WOBURN, MA 01801

510(k) NO: K001606
PHONE NO : 781-667-8893

DEVICE: REPROBEAD TSH ENZYME IMMUNOASSAY REAGENT KIT (CATALOG# 107)
SE DECISION MADE: 05-OCT-2000
510(k) STATEMENT

REPMEDIX CORP
ATTN: HAN-SOO KIM
86 CUMMINGS PARK,
WOBURN, MA 01801

510(k) NO: K001607
PHONE NO : 781-667-8893

DEVICE: REPROBEAD T3 ENZYME IMMUNOASSAY REAGENT KIT (CATALOG# 104)
SE DECISION MADE: 05-OCT-2000
510(k) STATEMENT

RETINALABS.COM
ATTN: FRANK TIGHE
1776 PEACHREE STREET
200 NORTH
ATLANTA, GA 30309

510(k) NO: K000418
PHONE NO : 800-793-1473

DEVICE: PDT DOSECALCULATOR, MODEL 80000
SE DECISION MADE: 24-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

RIVERSTONE RESOURCES SDN. BHD.
RILE)
ATTN: CHONG CHU MEE
LOT 21909, NO.5, LORONG HELAN
HINDIK KEPONG BARU INDUST. EST
KEPONG BARU, KUALA LUMPUR,

510(k) NO: K003232
PHONE NO : 603 636 8077

DEVICE: RS NITRILSTAT MEDICAL EXAMINATION GLOVES, POWDER FREE (NON-STE
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

ROCHE DIAGNOSTICS CORP.
ATTN: PRISCILLA A HAMILL
9115 HAGUE RD.
INDIANAPOLIS, IN 46250-0457

510(k) NO: K001468
PHONE NO : 317-576-3723

DEVICE: ELECSYS CA 15-3 TEST SYSTEM
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
ATTN: KAY A TAYLOR
9115 HAGUE RD.
INDIANAPOLIS, IN 46250-0457

510(k) NO: K002760
PHONE NO : 317-576-3544

DEVICE: ELECSYS DHEA-S CALSET
SE DECISION MADE: 05-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

ROLENCE ENTERPRISE CO. LTD.
ATTN: STERLING CHENG
18-3 LANE 231 FU CHUNG RD.
CHUNGLI 320,

510(k) NO: K001719
PHONE NO : 886 346 31999

DEVICE: Q-LUX PLASMA 100 LIGHT CURE UNIT
SE DECISION MADE: 10-OCT-2000
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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RONVIG INSTRUMENTS, LTD. ATTN: ANNETTE RAVN NEILSEN GL.VEJLEVEJ 57-59 DK-8721 DAUGAARD,	510(k) NO: K002168 PHONE NO : 45 75 895711	DEVICE: ASPIJECT SELF-ASPIRATING DENTAL INJECTION SYRINGE SE DECISION MADE: 13-OCT-2000 510(k) STATEMENT
RIEK MEDICAL SYSTEMS, LLC ATTN: ROBERT C JACKSON 16 TOBEY VILLAGE OFFICE PARK PITTSFORD, NY 14534	510(k) NO: K001295 PHONE NO : 716-249-0984	DEVICE: PIPER SE DECISION MADE: 25-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SAGE BIOPHARMA ATTN: GREG HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K002836 PHONE NO : 949-262-0411	DEVICE: MEDIA FOR GAMETE PREPARATION AND EMBRYO CULTURE SE DECISION MADE: 03-OCT-2000 510(k) STATEMENT
SCIMEDX CORP. ATTN: GARY LEHNUS 400 FORD RD. DENVER, NJ 07834	510(k) NO: K002169 PHONE NO : 973-625-8822	DEVICE: GLIADIN IGA ANTIBODY EIA DETECTION SYSTEM SE DECISION MADE: 19-OCT-2000 510(k) STATEMENT
SCIMEDX CORP. ATTN: GARY L EHNUS 400 FORD RD. DENVER, NJ 07834	510(k) NO: K002189 PHONE NO : 973-625-8822	DEVICE: GLIADIN IGG ANTIBODY EIA DETECTION SYSTEM SE DECISION MADE: 19-OCT-2000 510(k) STATEMENT
SECTRA-IMTEC AB ATTN: HERMAN COSTERWIJK 2001 EAST OAKSHORES DRIVE CROSSROADS, TX 76227	510(k) NO: K002936 PHONE NO : 940-440-9530	DEVICE: MODIFICATION TO IDS5 IMAGE DISPLAY SYSTEM SE DECISION MADE: 17-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SELF CARE, INC. ATTN: CAROL A ADILETTO 200 PROSPECT ST. WALHAM, MA 02154-3457	510(k) NO: K002867 PHONE NO : 781-647-3900	DEVICE: INVERNESS MEDICAL OVULATION PREDICTOR TEST SE DECISION MADE: 12-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SHANGHAI PT PLASTICS ENTERPRISE ATTN: CHANG T SUN 258 YUSHU RD. CANGQIAO TOWNSHIP SHONGJIANG COUNTY, SHANGHAI,	510(k) NO: K002814 PHONE NO : 862 157 814212	DEVICE: DISPOSABLE POWDERED VINYL SYNTHETIC EXAM GLOVES, WHITE COLOR SE DECISION MADE: 20-OCT-2000 510(k) STATEMENT
SHANGHAI PT PLASTICS ENTERPRISE ATTN: PETER WANG NO. 258, YUSHU ROAD CANGQIAO TOWNSHIP SONGJIANG COUNTY, SHANGHAI,	510(k) NO: K002870 PHONE NO : 011 862 157818521	DEVICE: DISPOSABLE POWDER FREE VINYL SYNTHETIC EXAM GLOVES, WHITE COLOR SE DECISION MADE: 16-OCT-2000 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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SIEMENS ELEMA AB ATTN: DAVE SIMARD ELECTROMEDICAL SYSTEMS GROUP 16 ELECTRONICS AVENUE DANVERS, MA 01923	510(k) NO: K002137 PHONE NO : 978-097-7737	DEVICE: CATHCOR DESKTOP SE DECISION MADE: 05-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SYSTEMS, INC. ATTN: JAMIE YIEH 186 WOOD AVENUE SOUTH ISELIN, NJ 08830	510(k) NO: K002179 PHONE NO : 732-321-4625	DEVICE: MAGNETOM ALLEGRA SYSTEM SE DECISION MADE: 11-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SYSTEMS, INC. ATTN: KATHLEEN RUTHERFORD 186 WOOD AVENUE SOUTH ISELIN, NJ 08830	510(k) NO: K003014 PHONE NO : 732-231-4779	DEVICE: SOMATOM EMOTION MS SE DECISION MADE: 12-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SYSTEMS, INC. ATTN: JUDI HOFFMAN 22010 S.E. 51ST ST. ISSAQUAH, WA 98029-7002	510(k) NO: K003125 PHONE NO : 425-557-1229	DEVICE: SONOLINE ELEGRA DIAGNOSTIC ULTRASOUND SYSTEM SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SYSTEMS, INC. ATTN: KATHLEEN RUTHERFORD 186 WOOD AVENUE SOUTH ISELIN, NJ 08830	510(k) NO: K003152 PHONE NO : 732-321-4779	DEVICE: SOMATOM SMILE SE DECISION MADE: 24-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SMART GLOVE CORP. SDN BHD IN CONJUNT LABELING CLAIM (50 MICROGRAMS OR LESS) ATTN: FOO K PU LOT 6487 BATU 5 3/4 JALAN KAPAR KLANG SELANGOR,	510(k) NO: K002568 PHONE NO : 603 391 6100	DEVICE: POLYMER COAT, POWDER FREE, LATEX EXAMINATION GLOVES WITH PROTE SE DECISION MADE: 03-OCT-2000 510(k) STATEMENT
SMITH & NEPHEW ENT. ATTN: GREG SPEDIN 2925 APPLING RD. BARTLETT, TN 38133	510(k) NO: K002702 PHONE NO : 901-373-0200	DEVICE: NEUROTOLOGY DRAPE, MODEL TED SE DECISION MADE: 26-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW ENT. ATTN: ALICIA FARAGE 2925 APPLING RD. BARTLETT, TN 38133	510(k) NO: K002737 PHONE NO : 901-373-0200	DEVICE: SMITH & NEPHEW PORPS & TORPS SE DECISION MADE: 12-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW ENT. ATTN: JEFFREY W COEB 2925 APPLING RD. BARTLETT, TN 38133	510(k) NO: K003214 PHONE NO : 901-373-0200	DEVICE: SMITH & NEPHEW PISTONS SE DECISION MADE: 31-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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SMITH & NEPHEW, INC.
ATTN: DEMETRIOS TSAKONAS
160 DASCOMB RD.
ANDOVER, MA 01810

510(k) NO: K002261
PHONE NO : 508-261-3775

DEVICE: MR-III
SE DECISION MADE: 23-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

SPINAL CONCEPTS, INC.
ATTN: DAVID M HOOPER
12012 TECHNOLOGY BLVD., #100
AUSTIN, TX 78727

510(k) NO: K002082
PHONE NO : 512-918-2700

DEVICE: SPEEDLINK TRANSVERSE CONNECTOR
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

SPINAL INNOVATIONS, LLC
ATTN: KEN RUSSELL
7850 STAGE HILLS BLVD.
SUITE 105
BARTLETT, TN 38133

510(k) NO: K002069
PHONE NO : 901-373-8855

DEVICE: ASCEND SPINAL FIXATION SYSTEM
SE DECISION MADE: 05-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

STACKHOUSE, INC.
ATTN: TOM GUTIERREZ
1100 BIRD CENTER DR.
PALM SPRINGS, CA 92262

510(k) NO: K003194
PHONE NO : 760-778-7255

DEVICE: STACKHOUSE LENS HOOD, MODEL SA-700/FS
SE DECISION MADE: 26-OCT-2000
510(k) STATEMENT

STARION INSTRUMENTS
ATTN: BRIAN GRIGSBY
20665 4TH ST.
SARATOGA, CA 95070

510(k) NO: K002547
PHONE NO : 408-741-8773

DEVICE: STARION INSTRUMENTS POWER POINT CAUTERY GRASPER/DISSECTOR
SE DECISION MADE: 20-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

STERLING MEDIVATIONS, INC.
ATTN: JOEL DOUGLAS
180 FERNDAL ROAD SOUTH
WAYZATA, MN 55391

510(k) NO: K002180
PHONE NO : 650-949-0407

DEVICE: SIMPLICITY DISPOSABLE PEN NEEDLE
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

STERLING MEDIVATIONS, INC.
ATTN: JOEL DOUGLAS
180 FERNDAL ROAD SOUTH
WAYZATA, MN 55391

510(k) NO: K002492
PHONE NO : 650-949-0470

DEVICE: SIMPLICITY SOFT INFUSION SET
SE DECISION MADE: 24-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K002732
PHONE NO : 616-323-7700

DEVICE: STRYKER NAVIGATION SYSTEM - ENT MODULE
SE DECISION MADE: 02-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

SUITER MEDICAL L.L.C.
ATTN: JAMES P SUITER
203 WEST 2ND STREET
MC COCK, NE 69001

510(k) NO: K002876
PHONE NO : 800-354-3450

DEVICE: JOBSITE ENHANCED MOBILITY CHAIR, MODEL JEM
SE DECISION MADE: 11-OCT-2000
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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SULTAN DENTAL PRODUCTS, LTD. ATTN: GEORGE WOLFE 242 SOUTH DEAN ST. ENGLEWOOD, NJ 07631	510(k) NO: K002581 PHONE NO : 201-894-5500	DEVICE: DURAGARD SODIUM FLUORIDE VARNISH SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SULZER ORTHOPEDICS, INC. OLY PATELLA ATTN: MITCHELL DHORITY 9900 SPECTRUM DR. AUSTIN, TX 78717	510(k) NO: K002335 PHONE NO : 512-432-9202	DEVICE: NATURAL-KNEE II SYSTEM-DURASUL TIBIAL INSERT AND DURASUL ALL-P SE DECISION MADE: 25-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SULZER ORTHOPEDICS, INC. ATTN: MITCHELL A DHORITY 9900 SPECTRUM DR. AUSTIN, TX 78717	510(k) NO: K002356 PHONE NO : 512-432-9900	DEVICE: NATURAL-KNEE II PATELLOFEMORAL JOINT PROSTHESIS SE DECISION MADE: 30-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SUN NUCLEAR CORP. ATTN: THOMAS L POWERS 425-A PINEDA COURT MELBOURNE, FL 32940	510(k) NO: K002444 PHONE NO : 407-259-6862	DEVICE: PRECISION DOSIMETRY ELECTROMETER, MODEL 1010 OR 206 SE DECISION MADE: 18-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SUN NUCLEAR CORP. ATTN: THOMAS L POWERS 425-A PINEDA COURT MELBOURNE, FL 32940	510(k) NO: K002446 PHONE NO : 407-259-6862	DEVICE: RE-ENTRANT CHAMBER, MODEL 1008 OR 44D SE DECISION MADE: 23-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SUNTECH MEDICAL INSTRUMENTS, INC. ATTN: GEORGE MYERS 377 ROUTE 17 HASBROUCK, NJ 07460	510(k) NO: K003004 PHONE NO : 201-727-1703	DEVICE: OSCAR 2, MODEL 222 SE DECISION MADE: 25-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SURGI-VISION, INC. ATTN: NANCY E TAYLOR 9250 RUMSEY RD., SUITE 100 COLUMBIA, MD 21045	510(k) NO: K002345 PHONE NO : 410-730-8998	DEVICE: SURGI-VISION URETHRAL COIL SE DECISION MADE: 11-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SURGICAL NAVIGATION TECHNOLOGIES, ATTN: ROGER WHITE 530 COMPTON STREET BROOMFIELD, CO 80020	510(k) NO: K000246 PHONE NO : 303-439-9709	DEVICE: RADIOCAMERAS EXTRACRANIAL SYSTEM SE DECISION MADE: 20-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
SURGICAL SPECIALITIES CORP. PRECISIONEDGE-CB MICROKRYPTOME BLADES ATTN: VIKKI M HOFFMAN 100 DENNIS DRIVE READING, PA 19606-3776	510(k) NO: K002849 PHONE NO : 610-404-1000	DEVICE: PRECISIONEDGE-ACC, PRECISIONEDGE-ACS, PRECISIONEDGE-LSK, AND P SE DECISION MADE: 18-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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SYNTHES
ATTN: JONATHAN GILBERT
1690 RUSSELL RD.
P.O. BOX 1766
PAOLI, PA 19301-1262

510(k) NO: K003061
PHONE NO : 610-647-9700

DEVICE: SYNTHES USS (10.0MM SIDE OPENING SCREWS)
SE DECISION MADE: 30-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: JONATHAN M GILBERT
P.O. BOX 1766
1690 RUSSELL ROAD
PAOLI, PA 19301-1222

510(k) NO: K994121
PHONE NO : 610-647-9700

DEVICE: SMALL STATURE USS
SE DECISION MADE: 17-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: BONNIE J SMITH
P.O. BOX 1766
1690 RUSSELL ROAD
PAOLI, PA 19301-1222

510(k) NO: K002361
PHONE NO : 610-647-9700

DEVICE: SYNTHES (USA) LOCKING PROXIMAL PLATING (L-PTP) SYSTEM
SE DECISION MADE: 31-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: THOMAS M MAGUIRE
1690 RUSSELL RD.
PAOLI, PA 19301

510(k) NO: K002729
PHONE NO : 610-647-9700

DEVICE: SYNTHES PROXIMAL HUMERAL NAIL
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

TECNO INSTRUMENTS (PVT.) LTD.
ATTN: SUSAN D GOLDSTEIN-FALK
55 NORTHERN BLVD., SUITE 200
GREAT NECK,, NY 11021

510(k) NO: K002257
PHONE NO : 203-431-1511

DEVICE: TECNO DISPOSABLE FINGERSWITCH PENCIL, MODEL 150-100
SE DECISION MADE: 19-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

THAYER MEDICAL CORP.
ATTN: DAVID T SLADEK
4575 SOUTH PALO VERDE RD.,
SUITE 337
TUCSON, AZ 85714

510(k) NO: K993101
PHONE NO : 520-790-5393

DEVICE: LITEAIRE
SE DECISION MADE: 26-OCT-2000

510(k) STATEMENT

THE ANSPACH EFFORT, INC.
ATTN: WILLIAM E ANSPACH III
4500 RIVERSIDE DR.
PALM BEACH GARDENS, FL 33410

510(k) NO: K002903
PHONE NO : 561-627-1080

DEVICE: ANSPACH ANGLED MICRANOSE ATTACHMENT
SE DECISION MADE: 24-OCT-2000
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: K002560
PHONE NO : 310-449-1399

DEVICE: SHEEP ANTI-HUMAN IGE IMMUNOFIXATION GRADE KIT
SE DECISION MADE: 26-OCT-2000

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: K002561
PHONE NO : 310-449-1399

DEVICE: SHEEP ANTI-HUMAN IGD IMMUNOFIXATION GRADE KIT
SE DECISION MADE: 26-OCT-2000

510(k) STATEMENT

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THE BINDING SITE, LTD. KIT ATTN: JAY H GELLER WEST TOWER, SUITE 4000 2425 WEST OLYMPIC BOULEVARD SANTA MONICA, CA 90404	510(k) NO: K002563 PHONE NO : 310-449-1399	DEVICE: SHEEP ANTI-HUMAN LAMBDA FREE LIGHT CHAIN IMMUNOFIXATION GRADE SE DECISION MADE: 26-OCT-2000 510(k) STATEMENT
THE BINDING SITE, LTD. IT ATTN: JAY H GELLER WEST TOWER, SUITE 4000 2425 WEST OLYMPIC BOULEVARD SANTA MONICA, CA 90404	510(k) NO: K002564 PHONE NO : 310-449-1399	DEVICE: SHEEP ANTI-HUMAN KAPPA FREE LIGHT CHAIN IMMUNOFIXATION GRADE K SE DECISION MADE: 26-OCT-2000 510(k) STATEMENT
THE GENETICS INSTITUTE ATTN: MARYANN KRANE 87 CAMBRIDGE PARK DRIVE CAMBRIDGE, MA 02140-2387	510(k) NO: K002350 PHONE NO : 617-665-8737	DEVICE: REFACIO LABORATORY STANDARD SE DECISION MADE: 05-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
TISSUE MEDICAL LASERS, INC. ATTN: DWIGHT ZURAWSKI 4432 ANAHEIM AVE., N.E. ALBUQUERQUE, NM 87113	510(k) NO: K000317 PHONE NO : 505-828-0508	DEVICE: SPECTRA-VRM Q-SWITCHED ND:YAG LASER SYSTEM, SPECTRA-VRM SE DECISION MADE: 27-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
TORNIER S.A. ATTN: DAVID W SCHLERF 200 GREGORY LANE SUITE C-100 PLEASANT HILL, CA 94523-3389	510(k) NO: K000003 PHONE NO : 925-356-2640	DEVICE: TORNIER TOTAL ELBOW PROSTHESIS SE DECISION MADE: 02-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
TOSHIBA AMERICA MEDICAL SYSTEMS, ATTN: DIANA THORSON 2441 MICHELLE DR. P.O. BOX 2068 TUSTIN, CA 92781-2068	510(k) NO: K002424 PHONE NO : 714-730-5000	DEVICE: 3D ANGIOGRAPHIC IMAGING SYSTEM, MODEL XIDF-100A SE DECISION MADE: 27-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
TOSHIBA AMERICA MRI, INC. ATTN: BRUCE CLARK 280 UTAH AVE. SOUTH SAN FRANCISCO, CA 94080	510(k) NO: K002522 PHONE NO : 650-872-2722	DEVICE: OPART, MODEL MRT-600 SE DECISION MADE: 25-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA
TOSHIBA AMERICA MRI, INC. ATTN: KEN NEEMER 280 UTAH AVE. SOUTH SAN FRANCISCO, CA 94080	510(k) NO: K002531 PHONE NO : 650-872-2722	DEVICE: EXCELART WITH PIANISSIMO, MODEL MRT-1501/P3 SE DECISION MADE: 26-OCT-2000 510(k) SUMMARY AVAILABLE FROM FDA

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TRAC ABOUT, INC.
ATTN: KEVIN WALLS
777 S. WADSWORTH BLVD.
BLDG.2. STE. 102
LAKEWOOD, CO 80226

510(k) NO: K001835
PHONE NO : 720-962-5412

DEVICE: IRV2000 INDIVIDUAL RECREATIONAL VEHICLE
SE DECISION MADE: 11-OCT-2000

510(k) STATEMENT

TUTOGEN MEDICAL U.S., INC.
ATTN: PJ PARDO
13709 PROGRESS BLVD.
BOX 19
ALACHUA, FL 32615

510(k) NO: K991296
PHONE NO : 904-462-2178

DEVICE: TUTIOPATCH
SE DECISION MADE: 06-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

UNILENS CORP., USA
T LENS
ATTN: CHARLOTTE B COUECOU
10431 72ND ST. NORTH
LARGO, FL 33777

510(k) NO: K002408
PHONE NO : 727-544-2531

DEVICE: AXION PLUS (METHAFILCON A) SOFT (HYDROPHILIC) ASPHERIC CONTRAC
SE DECISION MADE: 17-OCT-2000
510(k) STATEMENT

UNITED CHAIR MFG., LLC
ED #3018-ELEGANCE SERIES, UNITED #5018-MASTER SERIES
ATTN: DOUGLAS A HANEY
2097 SOUTH HAMILTON ROAD
SUITE 109
COLUMBUS, OH 43232

510(k) NO: K002318
PHONE NO : 614-759-7333

DEVICE: UNITED #1018-FREEDOM SERIES, UNITED #2018-COMFORT SERIES, UNIT
SE DECISION MADE: 11-OCT-2000

510(k) STATEMENT

UNITED PACIFIC CO., LTD.
ATTN: DANIEL YE HUA
219 SOUTH RAYMOND AVE
ALHAMERA, CA 91801

510(k) NO: K003010
PHONE NO : 626-458-8518

DEVICE: SPIRIT ACUPUNCTURE NEEDLE
SE DECISION MADE: 19-OCT-2000
510(k) STATEMENT

USA INSTRUMENTS, INC.
ATTN: RONY THOMAS
1515 DANNER DRIVE
AURORA, OH 44202

510(k) NO: K002482
PHONE NO : 330-562-1000

DEVICE: VISION 9000 PHASED ARRAY TORSO COIL
SE DECISION MADE: 17-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

USA INSTRUMENTS, INC.
ATTN: RONY THOMAS
1515 DANNER DRIVE
AURORA, OH 44202

510(k) NO: K002483
PHONE NO : 330-562-1000

DEVICE: POWER 5000 GENERAL PURPOSE COIL
SE DECISION MADE: 25-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

VALEO CORP.
ATTN: MARIAN HARDING COCHRAN
501 SOUTH ANDREWS AVENUE
FT. LAUDERDALE, FL 33301

510(k) NO: K002562
PHONE NO : 954-779-2500

DEVICE: PACIFIER THERMOMETER MODELS VT-901F, VT901C
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

VISIJET, INC.
ATTN: JUDY F GORDON
18732 SAGINAW
IRVINE, CA 92614

510(k) NO: K991124
PHONE NO : 949-854-6314

DEVICE: VISIJET HYDROKERATOME, MODEL 50
SE DECISION MADE: 20-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-OCT-2000 THROUGH 31-OCT-2000

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VITAL IMAGES, INC.
ATTN: ROBERT C SAMEC
3300 FERNROCK LANE NORTH
SUITE 200
PLYMOUTH, MN 55447

510(k) NO: K002519
PHONE NO : 612-915-8001

DEVICE: VITREA 2, VERSION 2.1
SE DECISION MADE: 19-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

VOGUE SHOPS, INC.
ATTN: TRACI V.A. EDWARDS
6225 POWERS AVE.
JACKSONVILLE, FL 32217

510(k) NO: K003022
PHONE NO : 408-543-2414

DEVICE: AERONEE PORTABLE NEBULIZER
SE DECISION MADE: 13-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

WESTAIM BIOMEDICAL INC.
ATTN: STEVE CHARTIER
ONE HAMPTON RD., SUITE 302
EXETER, NH 03833

510(k) NO: K001519
PHONE NO : 603-775-7300

DEVICE: ACTICOAT 7 DRESSING
SE DECISION MADE: 06-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

WRP SPECIALTY PRODUCTS SDN. BHD.
STERILE, CONTAINS 50 MICROGRAMS OR LESS OF TOTAL EXTRACTABL
ATTN: MOHD HAIZAN HUSSEIN
LOT11, JL.2, KAWASAN PERUSAHAAN
BANDAR BARU SLAK TINGGI
SELANGOR DAUHL EHSAN, SEPANG,

510(k) NO: K002975
PHONE NO : 60 387 069788

DEVICE: DERMAGRIP POWDER FREE POLYMER COATED LATEX EXAMINATION GLOVE S
SE DECISION MADE: 24-OCT-2000

510(k) SUMMARY AVAILABLE FROM FDA

XOMED, INC.
ATTN: MARTIN D SARGENT
6743 SOUTHPOINT DR. NORTH
JACKSONVILLE, FL 32216

510(k) NO: K002828
PHONE NO : 904-279-7586

DEVICE: XPS NITRO SYSTEM
SE DECISION MADE: 17-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

XOMED, INC.
ATTN: DAVID TIMLIN
6743 SOUTHPOINT DR. NORTH
JACKSONVILLE, FL 32216

510(k) NO: K002897
PHONE NO : 904-279-7532

DEVICE: TITANIUM MIDDLE EAR PROSTHESES
SE DECISION MADE: 11-OCT-2000
510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-OCT-2000 THROUGH 31-OCT-2000

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TOTAL 510(k)s THIS PERIOD	288
TOTAL WITH SUMMARIES	213
TOTAL WITH STATEMENTS	75