

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-FEB-2001 THROUGH 28-FEB-2001

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0301 '01 MAR -7 19:42

"O" CO., INC.
ATTN: DAVID D DALISE
600 PAISANO, N.E., SUITE A
ALBUQUERQUE, NM 87123

510(k) NO: K010142
PHONE NO : 505-293-0025

DEVICE: OCO DENTAL IMPLANT
SE DECISION MADE: 01-FEB-2001
510(k) STATEMENT

A & A MEDICAL, INC.
ATTN: JIHAD MANSOUR
9370 INDUSTRIAL TRACE
ALPHARETTA, GA 30004-3383

510(k) NO: K010056
PHONE NO : 770-343-8400

DEVICE: UTERINE MANIPULATOR INJECTOR CANNULA, STERILE, MODEL R 57-450
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

A.L.I. TECHNOLOGIES, INC.
ATTN: ROBERT MACNEIL
130- 10711 CAMBIE ROAD
RICHMOND, B.C.,

510(k) NO: K003762
PHONE NO : 604 279 5422

DEVICE: ALI 3D TOOL MODULE FOR MEDICAL IMAGES
SE DECISION MADE: 28-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

A.R.C. LASER AG
ATTN: DANIEL HOEFER
2417 SOUTH 3850 WEST
SALT LAKE CITY, UT 84120

510(k) NO: K003512
PHONE NO : 801-972-1311

DEVICE: LASER PACK I, LASER PACK II, PHACO PACK I, PHACO PACK II
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACE SURGICAL SUPPLY CO., INC.
ATTN: J. EDWARD CARCHIDI
1034 PEARL STREET
P.O. BOX 1710
BROCKTON, MA 02403

510(k) NO: K002075
PHONE NO : 508-588-3100

DEVICE: ACE SDS 3.75MM SCREW DENTAL IMPLANT
SE DECISION MADE: 02-FEB-2001

510(k) STATEMENT

ACTHERM, INC.
ACT2000+, ACT2010+, ACT2020+
ATTN: RICHARD HSIEH
10TH F. #43 KUAN-MIN 6 ROAD
JUBEI, HSINCHU,

510(k) NO: K010238
PHONE NO : 886 355 37315

DEVICE: ACTHERM DIGITAL CLINICAL THERMOMETER, MODELS ACT2000, ACT2010,
SE DECISION MADE: 06-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADAC LABORATORIES
ATTN: JANICE E BROWN
540 ALDER DR.
MILPITAS, CA 95035

510(k) NO: K002237
PHONE NO : 408-468-3766

DEVICE: P3IMRT TM
SE DECISION MADE: 02-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

AESULAP, INC.
ATTN: LISA M MILLINGTON
944 MARCON BLVD
ALLENTOWN, PA 18109

510(k) NO: K003608
PHONE NO : 800-258-1946

DEVICE: SOVEREIGN BIPOLAR INSTRUMENTS FOR GYNECOLOGY
SE DECISION MADE: 20-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K003612
PHONE NO : 800-258-1946

DEVICE: MICROSPEED EC MOTOR SYSTEM GD650/GD653
SE DECISION MADE: 20-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

945-0120

LST 103

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AGILENT TECHNOLOGIES
ATTN: GRETEL LUMLEY
1201 "B" N. RICE AVE
OXNARD, CA 93030

510(k) NO: K003940
PHONE NO : 800-235-5941

DEVICE: 2010 PLUS HOLTET FOR WINDOWS
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES DEUTSCHLAND G510(k) NO: K002758
DULE, AGILENT INVASIVE PRESSURE MODULE, MODEL M1175A/76A
ATTN: EGOH PFEIL
HERRENBERGER STRASSE 130
D 71034 BOEBLINGEN
BOEBLINGEN,,

PHONE NO : 031-464-7223

DEVICE: AGILENT COMPONENT MONITORING SYSTEM, AGILENT CARDIAC OUTPUT MC
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K010048
PHONE NO : 978-659-3173

DEVICE: M2376A DEVICELINK SYSTEM
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K010342
PHONE NO : 978-659-3173

DEVICE: M2376A DEVICELINK SYSTEM, MODEL M2376A
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K010211
PHONE NO : 847-473-1500

DEVICE: STERILE NITRILE POWDER-FREE EXAMINATION GLOVES
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLERGAN, INC.
ATTN: PAUL J NOWACKI
2525 DUPONT DR.
IRVINE, CA 92612

510(k) NO: K003252
PHONE NO : 714-246-6761

DEVICE: COMPLETE BRAND MULTI-PURPOSE SOLUTION
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLERGAN, INC.
ATTN: MARK O'DONNELL
2525 DUPONT DR.
IRVINE, CA 92612

510(k) NO: K003638
PHONE NO : 714-246-2226

DEVICE: MOJAVE CATARACT EXTRACTION SYSTEM
SE DECISION MADE: 13-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN BIOCURVE, INC.
LENS FOR DAILY WEAR (CLEAR & BLUE VISIBILITY TINT, LATHE
ATTN: MARTIN DALSIK
623 GLACIER DR.
GRAND JUNCTION, CO 81503

510(k) NO: K001585
PHONE NO : 970-243-5490

DEVICE: BIOCURVE SOFT (METHAFILCON A) SPHERICAL AND TORIC SOFT CONTACT
SE DECISION MADE: 13-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANC IMPORT & EXPORT CO. LTD.
ATTN: WILLIAM ZHANG
4309 MURWICK DRIVE
ARLINGTON, TX 76016

510(k) NO: K002910
PHONE NO : 817-572-6790

DEVICE: HOLY DRAGON ACUPUNCTURE NEEDLES
SE DECISION MADE: 07-FEB-2001
510(k) STATEMENT

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APPLIED BIOTECH, INC.
ATTN: DAVE D SMITH
10237 FLANDERS CT.
SAN DIEGO, CA 92121

510(k) NO: K003160
PHONE NO : 858-713-9614

DEVICE: APPLIED BIOTECH, INC. SURESTEP ER DRUG SCREEN TEST
SE DECISION MADE: 08-FEB-2001
510(k) STATEMENT

APPLIED MEDICAL
ATTN: ANIL BHALANI
22872 AVENIDA EMPRESA
RANCHO SANTA MARGARITA, CA 92688

510(k) NO: K003443
PHONE NO : 949-713-8327

DEVICE: SUCTION IRRIGATOR
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

APPRIVA MEDICAL, INC.
-09-90, MV-03-10-90, MV-03-11-90, MV-03-09-120, MV-03-10-1
ATTN: MICHAEL KOLBER
777 NORTH PASTORIA AVENUE
SUNNYVALE, CA 94086

510(k) NO: K002054
PHONE NO : 650-691-4595

DEVICE: X-SEPT TRANSSEPTAL SHEATH AND TRANSITION CATHETER, MODEL MV-03
SE DECISION MADE: 16-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

AURORA IMAGING TECHNOLOGY, INC.
ATTN: JAMES J ROGERS
46 JONSPIN RD.
WILMINGTON, MA 01887

510(k) NO: K003651
PHONE NO : 800-858-8667

DEVICE: AURORA
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

B-K MEDICAL A/S
ATTN: VILLY BRAENDER
SANDTOFTEN 9
GENIOFTE,

510(k) NO: K003041
PHONE NO : 011 454 5970100

DEVICE: ULTRASOUND SCANNER TYPE 2101
SE DECISION MADE: 07-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BANTA HEALTHCARE
ATTN: YOLNDA SMITH
PO BOX 4341
CROFTON, MD 21114

510(k) NO: K003749
PHONE NO : 410-451-0639

DEVICE: 100% 30G POLYPROPYLENE SPUNBOND ISLATION GROWN
SE DECISION MADE: 23-FEB-2001
510(k) STATEMENT

BAXTER HEALTHCARE CORP.
ATTN: ROBERT L WILKINSON
1620 WAUKEGAN RD., MPR-A2E
MCGAW PARK, IL 60085

510(k) NO: K002210
PHONE NO : 847-473-6335

DEVICE: SYNIRA DIALYZER, MODEL SYNIRA 120, 160
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYER CORP.
ATTN: FREDRICK CLERIE
511 BENEDICT AVE.
TARRYTOWN, NY 10591-5097

510(k) NO: K003796
PHONE NO : 914-524-2954

DEVICE: ADVIA 120 HEMATOLOGY
SE DECISION MADE: 05-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYLIS MEDICAL CO., INC.
CATHETER, BAYLIS MEDICAL CONNECTOR CABLE
ATTN: KRIS SHAH
5160 EXPLORER DRIVE, UNIT 5
MISSISSAUGA,

510(k) NO: K990284
PHONE NO : 905 602 4875

DEVICE: BAYLIS MEDICAL RF SEPTOSTOMY GENERATOR, NYKANEN RF SEPTOSTOMY
SE DECISION MADE: 01-FEB-2001
510(k) STATEMENT

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ED BECTON DICKINSON VACUTAINER SYS510(k) NO: K003461
ATTN: M. WENDY BOSSHARDT PHONE NO : 201-847-6280
1 BECTON DR.
FRANKLIN LAKES, NJ 07417-1880

DEVICE: ED VACUTAINER PASSIVE SHIELDING BLOOD COLLECTION NEEDLE
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC. 510(k) NO: K010064
ATTN: STAN SUGRUE PHONE NO : 305-380-4552
11800 SW 147TH AVE.
MIAMI, FL 33196-2500

DEVICE: 4C-ES CELL, MODELS 7547187, 7547188, 7547189, 7547190
SE DECISION MADE: 07-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC. 510(k) NO: K010066
ATTN: STAN SUGRUE PHONE NO : 305-380-4552
11800 SW 147TH AVE.
MIAMI, FL 33196-2500

DEVICE: 5C-ES CELL CONTROL, MODELS 7547191, 7547192
SE DECISION MADE: 07-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BENTEC MEDICAL, INC. 510(k) NO: K002650
ATTN: DAVID TUCKER PHONE NO : 530-406-3333
1380 EAST BEAMER ST.
WOODLAND, CA 95776

DEVICE: VAN ANGLE DILATION, EMERALD GUIDEWIRE, MODEL VAD6, 502-726
SE DECISION MADE: 16-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOCOMPOSITES LTD. 510(k) NO: K003641
ATTN: J. STEPHEN BRATT PHONE NO : 441 782 206500
ETRUSCAN ST., ETRURIA
STOKE ON TRENT,

DEVICE: BIOLOK SCREW, BIOSTEON SCREW
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOLUCENT, INC. 510(k) NO: K003795
ATTN: STEVE GEX PHONE NO : 949-349-1380
27121 ALISO CREEK ROAD
SUITE 125
ALISO VIEJO, CA 92656

DEVICE: BIOLUCENT MAMMOGRAPHY CUSHION
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOMERICA, INC. 510(k) NO: K003856
ATTN: JAY SINGH PHONE NO : 949-645-2111
1533 MONROVIA AVE.
NEWPORT BEACH, CA 92663

DEVICE: EZ-HOG URINE (PREGNANCY TEST)
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC. 510(k) NO: K003493
ATTN: SARA A BAILEY PHONE NO : 219-372-1568
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581-0587

DEVICE: 3I CALCIUM SODIUM PHOSPHATE BONE CEMENT
SE DECISION MADE: 09-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC. 510(k) NO: K010212
ATTN: CAROL LAUSTER PHONE NO : 219-267-6639
AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581-0587

DEVICE: OFFSET TIBIAL TRAY
SE DECISION MADE: 14-FEB-2001
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BIONX IMPLANTS, INC. 40,172060,173240,173260 ATTN: TULJA ANNALA HERMIANKATU 6-8 L TAMPERE,	510(k) NO: K003659 PHONE NO : 358 331 65600	DEVICE: PLGA PIN, MODEL 171120,171140,171520,171540,171560,172020,1720 SE DECISION MADE: 20-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIONX IMPLANTS, LTD. ATTN: TULJA ANNALA HERMIANKATU 6-8 L TAMPERE,	510(k) NO: K003757 PHONE NO : 358 331 65600	DEVICE: THERMOFX MESH SE DECISION MADE: 07-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPOOL INTL., INC. ATTN: MICHAEL D BICK 6025 NICOLLE ST., SUITE D VENTURA, CA 93003	510(k) NO: K002642 PHONE NO : 805-654-0643	DEVICE: MINIQUANT D-DIMER, MODEL 1447 SE DECISION MADE: 05-FEB-2001 510(k) STATEMENT
BIOSOUND ESAOTE, INC. ATTN: COLLEEN HITTLE 8000 CASTLEWAY DR. INDIANAPOLIS, IN 46250	510(k) NO: K010057 PHONE NO : 317-849-1793	DEVICE: MODIFICATION TO ARTOSCAN M SE DECISION MADE: 02-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: ANDREA BOUMIS 2710 ORCHARD PARKWAY SAN JOSE, CA 95134	510(k) NO: K003782 PHONE NO : 408-895-3625	DEVICE: CONSTELLATION CATHETER, MODEL 8031 SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB, AG ATTN: 100 MARINE PARKWAY SUITE 305 REDWOOD CITY, CA 94065	510(k) NO: K003268 PHONE NO :	DEVICE: Z-TOUCH SE DECISION MADE: 22-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BUCK MEDICAL RESEARCH D, 3.308, 3.310,3.312, 3.314 3.316 ATTN: REBECCA ELLIS 2811 LEMMON AVE., SUITE 201 DALLAS, TX 75204	510(k) NO: K010343 PHONE NO : 214-522-5780	DEVICE: BMR DENTAL IMPLANT SYSTEM, MODEL 3.3XX, EITHER HA OR TPS COATE SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. ATTN: CAROL VIERLING 13183 HARLAND DRIVE COVINGTON, GA 30014	510(k) NO: K010169 PHONE NO : 770-385-2347	DEVICE: BARD UTRAVVERSE SMALL VESSEL PTA BALLOON DILATATION CATHETER SE DECISION MADE: 13-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. HOOK TIP, CORBITT SPATULA TIP, BALL TIP, NEEDLE TIP ATTN: KERRY CHUNKO 700 EAST 22ND ST LAWRENCE, KS	510(k) NO: K010444 PHONE NO : 785-843-7782	DEVICE: ADVANTAGE SINGLE-USE ELECTROSURGICAL ATTACHMENT-J-HOOK TIP, L- SE DECISION MADE: 28-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA

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CARDIOMEDICS, INC.
ATTN: JOHN HUTCHINS
18872 BARDEEN AVE.
IRVINE, CA 92612

510(k) NO: K010261
PHONE NO : 949-863-2500

DEVICE: CARDIOMEDICS BCP SYSTEM
SE DECISION MADE: 28-FEB-2001
510(k) STATEMENT

CARL ZEISS, INC.
ATTN: SCOTT A MARGOLIN
ONE ZEISS DR.
THORNWOOD, NY 10594

510(k) NO: K003885
PHONE NO : 914-681-7880

DEVICE: VISULAS YAG II
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CATHETER INNOVATIONS, INC.
ATTN: ROGER L RICHINS
3598 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104-4859

510(k) NO: K010349
PHONE NO : 801-954-8444

DEVICE: DUAL LUMEN MIDLINE CATHETER
SE DECISION MADE: 28-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CIBA-GEIGY CORP.
ATTN: STEVEN DOWDLEY
11460 JOHNS CREEK PKWY.
DULUTH, GA 30136-1518

510(k) NO: K003586
PHONE NO : 678-415-3897

DEVICE: FOCUS DAILIES (NELFILCON A) ONE-DAY CONTACT LENSES
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

COALESCENT SURGICAL
ATTN: MICHAEL A DANIEL
559 EAST WEDDELL DR.
SUNNYVALE, CA 94089

510(k) NO: K003958
PHONE NO : 415-407-0223

DEVICE: COALESCENT U-CLIP DELIVERY AND DISPOSAL DEVICE
SE DECISION MADE: 06-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CODMAN & SHURLEFF, INC.
ATTN: JAMES M FLAHERTY
325 PARAMOUNT DR.
RAYNHAM, MA 02767-0350

510(k) NO: K003549
PHONE NO : 508-880-8404

DEVICE: CODMAN CRANIOSORB ABSORBABLE FIXATION SYSTEM PURPLE RIVETS
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CORIN U.S.A.
ATTN: JOEL K BAITTS
10500 UNIVERSITY CENTER DR.,
SUITE 190
TAMPA, FL 33612

510(k) NO: K003666
PHONE NO : 813-977-4469

DEVICE: TAPER-FIT TOTAL HIP SYSTEM
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CORIN U.S.A.
ATTN: JOEL K BAITTS
10500 UNIVERSITY CENTER DR.,
SUITE 190
TAMPA, FL 33612

510(k) NO: K010243
PHONE NO : 813-977-4469

DEVICE: TRI-FIT FEMORAL STEM
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CORINTHIAN MEDICAL LTD.
ATTN: DAGMAR MASER
AMSTEL 320-1
AMERSDAM,

510(k) NO: K003567
PHONE NO : 312 042 89591

DEVICE: SERENOCEM, MODEL BC 010
SE DECISION MADE: 12-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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CORTEX BIOPHYSIK GMBH
ATTN: ART WARD
962 ALLEGRO LANE
APOLLO BEACH, FL 33572

510(k) NO: K001631
PHONE NO : 813-645-2855

DEVICE: CORTEX METAMAX
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

CURON MEDICAL, INC.
MODEL S400
ATTN: THOMAS C WEHMAN
735 PALOMAR ST.
SUNNYVALE, CA 94086

510(k) NO: K010210
PHONE NO : 408-733-9910

DEVICE: CONTROL MODULE ALGORITHM ENHANCEMENT FOR THE MODEL S500-ST AND
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

DADE BEHRING, INC.
ATTN: LORRAINE H PIETRAK
GLASGOW BUSINESS COMMUNITY;
BLDG. 500 MAIL BOX 514
P.O. BOX 6101, NEWARK, DE 19714-6101

510(k) NO: K003419
PHONE NO : 302-631-6279

DEVICE: RCRP FLEX REAGENT CARTRIDGE
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K003870
PHONE NO : 302-631-6276

DEVICE: THROMBOREL S
SE DECISION MADE: 20-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: GEORGE M PLUMMER
GLASGOW BUSINESS COMMUNITY;
BLDG. 500 P.O. BOX 6101
NEWARK, DE 19714-6101

510(k) NO: K003963
PHONE NO : 302-631-9798

DEVICE: DIMENSION PSA FLEX REAGENT CARTRIDGE
SE DECISION MADE: 28-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: RICHARD M VAUGHT
GLASCO B500 M.S. 514
P.O. BOX 6101
NEWARK, DE 19714-6101

510(k) NO: K010208
PHONE NO : 302-631-6567

DEVICE: DIMENSION ENZYMATIC CARBONATE (ECO2) CALIBRATOR, CATALOG DC137
SE DECISION MADE: 20-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

DEPUY ORTHOPAEDICS, INC.
ATTN: MARCIA J ARENTZ
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581-0988

510(k) NO: K003800
PHONE NO : 219-371-4944

DEVICE: AML HIP PROSTHESIS
SE DECISION MADE: 09-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

DERMATOLOGIC LAB & SUPPLY, INC.
ATTN: DEBORAH GRAFELMAN
608 13TH AVE.
COUNCIL BLUFFS, IA 51501

510(k) NO: K010025
PHONE NO : 712-323-3269

DEVICE: ELECTRICATOR MODEL 26000
SE DECISION MADE: 22-FEB-2001
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DIAGNOSTIC PRODUCTS CORP. MODEL L2KH02 ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K003597 PHONE NO : 310-645-8200	DEVICE: IMMULITE HOMOCYSTEINE MODEL LKH01 / IMMULITE 2000 HOMOCYSTEINE SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTIC PRODUCTS CORP. MULITE 2000 CK-MB, MODEL L2KMB2 (200 TESTS), L2KMB6 (600) ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K004002 PHONE NO : 310-645-8200	DEVICE: IMMULITE CK-MB, MODEL LKMB1 (100 TESTS), LKMB5 (500 TESTS); IM SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTICA STAGO, INC. ATTN: ANDREW LOC B LE FIVE CENTURY DR. PARSIPPANY, NJ 07054	510(k) NO: K003767 PHONE NO : 973-631-1200	DEVICE: ASSERACHROM HPIA TEST KIT SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTICA, INC. ATTN: YOLANDA SMITH P.O. BOX 4341 CROFTON, MD 21114	510(k) NO: K002756 PHONE NO : 410-451-0639	DEVICE: EASE-A-CULT SE DECISION MADE: 23-FEB-2001 510(k) STATEMENT
DISETRONIC MEDICAL SYSTEMS AG D D SUBCUTANEOUS INFUSION SET ATTN: DAVID E CHADWICK 5151 PROGRAM AVENUE ST. PAUL, MN 55112-1014	510(k) NO: K003977 PHONE NO : 763-795-5277	DEVICE: DISETRONIC RAPID SUBCUTANEOUS INFUSION SET AND DISTERONIC RAPI SE DECISION MADE: 15-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
DUFNER INSTRUMENTE GMBH ATTN: DAGMAR MASER AMSTEL 320-I AMSTERDAM,	510(k) NO: K002877 PHONE NO : 312 042 89591	DEVICE: MICTEC ENDOSCOPES AND ACCESSORIES SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
DUO-DENT DENTAL IMPLANT SYSTEMS ATTN: MICHAEL H VOVOLKA P.O. BOX 848 GRAYSLAKE, IL 60030	510(k) NO: K010386 PHONE NO : 847-856-0355	DEVICE: DUO-DENT DENTAL IMPLANT SE DECISION MADE: 27-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: JON CAPAROTTA 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K010179 PHONE NO : 973-299-9022	DEVICE: EBI VUECATH SPINAL ENDOSCOPIC SYSTEM SE DECISION MADE: 09-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EDAP TECHNOMED, INC. ATTN: SCOTT J MINDREBO 100 PINNACLE WAY, SUITE 100 NORCROSS, GA 30071	510(k) NO: K003529 PHONE NO : 770-446-9950	DEVICE: SONOLITH PRAKTIS, ENDOUROLOGY TABLE PRAKTIS SE DECISION MADE: 12-FEB-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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ENVIRONMENTAL TEST SYSTEMS, INC. ATTN: BRUCE G PIEKARSKI P.O. BOX 4659 ELKHART, IN 46514	510(k) NO: K003615 PHONE NO : 219-262-2060	DEVICE: STERICHEK SENSITIVE-FEED WATER AND RINSE WATER REAGENT STRIPS SE DECISION MADE: 01-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
ETZEM TECHNOLOGIES, INC. ATTN: AHAVA SHEIN 20 HATA'AS ST. BEIT HAPA'AMON BOX 124 KFAR SABA,	510(k) NO: K003648 PHONE NO : 972 976 70002	DEVICE: FREEDLAND TENSION SYSTEM SE DECISION MADE: 23-FEB-2001 510(k) STATEMENT
EXACTECH, INC. ATTN: GARY J MILLER 2320 N.W. 66TH COURT GAINESVILLE, FL 32653	510(k) NO: K000943 PHONE NO : 352-377-1140	DEVICE: CEMEX SYSTEM GUN APPLICATION VERSION SE DECISION MADE: 08-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EXACTECH, INC. ATTN: LISA SIMPSON 2320 N.W. 66TH CT. GAINESVILLE, FL 32653	510(k) NO: K010081 PHONE NO : 352-377-1140	DEVICE: ACUMATCH L-SERIES UNIPOLAR ENDOPROSTHESIS SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EXACTECH, INC. IES HIGH OFF-SET NECK SEGMENT, M-SERIES LOW OFF-SET NECK S ATTN: GARY J MILLER 2320 N.W. 66TH CT. GAINESVILLE, FL 32653	510(k) NO: K010120 PHONE NO : 352-377-1140	DEVICE: MODIFICATION TO EXACTECH ACUMATCH INTEGRATED HIP SYSTEM, M-SER SE DECISION MADE: 09-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EXCEL TECH. LTD. ATTN: SONJA MARKEZ 2568 BRISTOL CIRCLE OAKVILLE, ONTARIO,	510(k) NO: K010091 PHONE NO : 905 829 5300	DEVICE: EEG WITH VIDEO, MODEL EX-NW SE DECISION MADE: 01-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EXCEL TECH. LTD. ATTN: SONJA MARKEZ 2568 BRISTOL CIRCLE OAKVILLE, ONTARIO,	510(k) NO: K010150 PHONE NO :	DEVICE: 64 CHANNEL EEG / MODEL NUMBER EX-NW-64 SE DECISION MADE: 09-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
EXELINT INTERNATIONAL COMPANY ATTN: ARMAND HAMID 5840 W. CENTINELA AVENUE LOS ANGELES, CA 90231-3194	510(k) NO: K003627 PHONE NO : 310-649-0707	DEVICE: EXEL SECURE TOUCH SAFETY A.V. FISTULA NEEDLE SET SE DECISION MADE: 08-FEB-2001 510(k) STATEMENT
EYETECT, L.L.C. ATTN: REBECCA M CUETO 10 MADONNA COURT BELLEVILLE,, IL 62223	510(k) NO: K003644 PHONE NO : 618-235-8609	DEVICE: EYETECT TREMOR MONITOR UNIT (TMU) SE DECISION MADE: 01-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA

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FADASSI MEDICAL, INC.
ATTN: RAYMOND RIDDLE
7601-B MURPHY DRIVE
MIDDLETOWN, WI 53562

510(k) NO: K003665
PHONE NO : 608-831-0025

DEVICE: FADASSI MEDICAL FM-1 NO BLENDER
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

FEMINICA INC.
ATTN: DENIS H DUBOIS
3216 MONSABRE
MONTREAL, QUEBEC,

510(k) NO: K003540
PHONE NO : 514 875 4422

DEVICE: (DISPOSABLE) VAGINAL SPECULUM
SE DECISION MADE: 09-FEB-2001
510(k) STATEMENT

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

510(k) NO: K003776
PHONE NO : 207-666-8190

DEVICE: MICROTARGETING DRIVE SYSTEM
SE DECISION MADE: 23-FEB-2001
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: K003946
PHONE NO : 414-544-3894

DEVICE: SIGNA SP 0.5T ROTATING HORIZONTAL BODY COIL
SE DECISION MADE: 27-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K010336
PHONE NO : 262-544-3894

DEVICE: ADVANTAGE WINDOWS CT/PET FUSION
SE DECISION MADE: 16-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

GEBAUER CO.
ATTN: DENISE E SPELLMAN
9410 ST. CATHERINE AVE.
CLEVELAND, OH 44104

510(k) NO: K002596
PHONE NO : 216-271-0910

DEVICE: GEBAUER'S FLURO ETHYL, MODEL 0386-0002-09
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

GLOBAL ENDOSCOPY, INC.
ATTN: NICK MIRCEA
914 W. ESTES CT.
SCHAUMBURG, IL 60193-4426

510(k) NO: K003806
PHONE NO : 847-301-2733

DEVICE: URETEROSCOPES
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

GLOBAL ENDOSCOPY, INC.
ATTN: NICK MIRCEA
914 W. ESTES CT.
SCHAUMBURG, IL 60193-4426

510(k) NO: K003807
PHONE NO : 847-301-2733

DEVICE: CYSTOSCOPES
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

GUIDANT CARDIAC AND VASCULAR SURGE510(k) NO: K003495
ATTN: JACQUELINE J JACKSON PHONE NO : 650-470-6200
1525 O'BRIEN DR.
MENLO PARK, CA 94025

DEVICE: ANCIURE ILLIAC BALLOON CATHETER
SE DECISION MADE: 07-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

GUTHRIE MEDICARE PRODUCTS (NS) SDN510(k) NO: K003922
ATTN: SUSAN D GOLDSTEIN-FALK PHONE NO : 516-482-9001
55 NORTHERN BLVD., SUITE 200
GREAT NECK, NY 11021

DEVICE: NITRILE EXAMINATION GLOVES (POWERED)
SE DECISION MADE: 15-FEB-2001
510(k) STATEMENT

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GUTHRIE MEDICARE PRODUCTS (NS) ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD., SUITE 200 GREAT NECK, NY 11021	SDN510(k) NO: K003985 PHONE NO : 203-431-1511	DEVICE: POWDERFREE NITRILE PATIENT EXMINATION GLOVE SE DECISION MADE: 09-FEB-2001 510(k) STATEMENT
HAENGLIM SEOWON CORP. ATTN: YUN CHOL CHO 34-69 LEAVITT ST. FLUSHING, NY 11354	510(k) NO: K002827 PHONE NO : 718-886-4469	DEVICE: MAC ACUPUNCTURE NEEDLE SE DECISION MADE: 28-FEB-2001 510(k) STATEMENT
HAYES MEDICAL, INC. ATTN: WILLIAM J GRIFFIN 1115 WINDFIELD WAY, SUITE 100 EL DORADO HILLS, CA 95762-9623	510(k) NO: K003649 PHONE NO : 916-355-7156	DEVICE: TRITON HIP SYSTEM SE DECISION MADE: 23-FEB-2001 510(k) STATEMENT
HEALIHONICS, INC. ATTN: T. WHIT ATHEY 12300 TWINEROOK PARKWAY SUITE 625 ROCKVILLE, MD 20852	510(k) NO: K003507 PHONE NO : 301-770-9590	DEVICE: MEDRELIEF SE DECISION MADE: 21-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
HELPTechnologies ATTN: ROBERT J BARD 24312 ARMADA DR. DANA POINT, CA 92629	510(k) NO: K003915 PHONE NO : 949-240-1290	DEVICE: ACCUFUSER; ACCUFUSER PLUS SE DECISION MADE: 15-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
HERAEUS KULZER, INC. ATTN: CHERYL ZIMMERMAN 4315 SOUTH LAFAYETTE BLVD. SOUTH BEND, IN 46614-2517	510(k) NO: K003930 PHONE NO : 219-299-6662	DEVICE: FLEXTIME MAGNUM 360 SE DECISION MADE: 01-FEB-2001 510(k) STATEMENT
HEYER AMERICA, INC. ATTN: ART WARD 962 ALLEGRO LANE APOLLO BEACH, FL 33572	510(k) NO: K001988 PHONE NO : 813-645-2855	DEVICE: MODULAR SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
HORIZON MEDICAL PRODUCTS, INC. ATTN: PENNY M NORHCUTT 1 HORIZON WAY MANCHESTER, GA 31816	510(k) NO: K010189 PHONE NO : 706-846-3126	DEVICE: VORTEX ACCESS SYSTEM SE DECISION MADE: 12-FEB-2001 510(k) STATEMENT
HOVEROUND CORP. ATTN: TONY DIGIOVANNI 2151 WHITFIELD INDUSTRIAL WAY SARASOTA, FL 34243	510(k) NO: K010075 PHONE NO : 941-739-6200	DEVICE: TEKNIQUE SE DECISION MADE: 14-FEB-2001 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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HOWMEDICA OSTEONICS CORP. ATTN: MARY-CATHERINE DILLON 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K001147 PHONE NO : 201-760-8117	DEVICE: ENHANCED POLYETHYLENE KNEE PROSTHESES SE DECISION MADE: 15-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
I.C. MEDICAL, INC. ATTN: CRAIG HARSHMAN 2002 WEST QUAIL AVE PHOENIX, AZ 85027	510(k) NO: K003840 PHONE NO : 623-780-0700	DEVICE: CRYSTAL VISION #250D SMOKE EVACUATOR SYSTEM WITH ACCESSORIES SE DECISION MADE: 01-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
IGEL VISIONCARE PTE LID. NIACI LENSES FOR DAILY WEAR ATTN: JOHN M SZABOCSIK 203 NORTH WABASH AVENUE SUITE 1200 CHICAGO, IL 60601	510(k) NO: K003833 PHONE NO : 312-553-0828	DEVICE: SPECIALTY 55 & MULTIFOCAL (METHAFILCON A) SOFT (HYDROPHILIC CC SE DECISION MADE: 13-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
INFUSION DEVICES, INC. ATTN: PAUL E DRYDEN 6329 W. WATERVIEW CT. MCCORDSVILLE, IN 46055	510(k) NO: K003854 PHONE NO : 317-335-3780	DEVICE: INTRAVASCULAR ADMINISTRATION SET SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
INTEGRATED ORBITAL IMPLANTS, INC. ATTN: FLOYD G LARSON 4329 GRAYDON ROAD SAN DIEGO, CA 92130	510(k) NO: K003338 PHONE NO : 858-792-1235	DEVICE: BIO-EYE II ORBITAL IMPLANT SE DECISION MADE: 07-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
INTERNATIONAL DENTAL RESEARCH ATTN: PAMELA PAPINEAU 5 WHITCOMB AVE. AYER, MA 01432	510(k) NO: K010219 PHONE NO : 978-772-3552	DEVICE: CHALLENGER DIRECT COMPOSITE SE DECISION MADE: 21-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
INTERSECT SYSTEMS, INC. ATTN: JOAN CATHEY P.O. BOX 2219 LONGVIEW, WA 98632	510(k) NO: K003892 PHONE NO : 360-577-1062	DEVICE: TOTAL BILIRUBIN REAGENT SE DECISION MADE: 20-FEB-2001 510(k) STATEMENT
INVACARE CORP. LYNX SX-3P, LYNX LX-3, LYNX LX-3, ATTN: RAE A FARROW ONE INVACARE WAY ELYRIA, OH 44036	510(k) NO: K010135 PHONE NO : 440-329-6356	DEVICE: MODELS LYNX AND PANTHER MOTORIZED SCOOTERS, MODELS LYNX SX-3, SE DECISION MADE: 16-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
IOP, INC. ATTN: JASON MALECKA 3151 AIRWAY AVE., BLDG. I-1 COSTA MESA, CA 92626	510(k) NO: K003646 PHONE NO : 714-549-1185	DEVICE: SUTUREGROOVE WEIGHT SIZING SET SE DECISION MADE: 22-FEB-2001 510(k) STATEMENT

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FROM IMAGING, INC.
ATTN: ROMAN KRYSYNIAK
3720 SOUTH LIPAN ST.
ENGLEWOOD, CO 80110

510(k) NO: K010304
PHONE NO : 303-762-1950

DEVICE: MKR-2000 MOBILE X-RAY UNIT
SE DECISION MADE: 12-FEB-2001
510(k) STATEMENT

IS2 RESEARCH INC.
ATTN: VICTOR WOODBURN
20 GURDWARA RD., BAYS 3-6
NEPEAN, ONTARIO,

510(k) NO: K003882
PHONE NO : 613 228 8755

DEVICE: NUCAMMA BI90
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ITAMAR MEDICAL (C.M.) 1997 LTD.
ATTN: AHAVA STEIN
P.O.B. 454
GINOT SHOMRON 44853,

510(k) NO: K001852
PHONE NO : 972 979 20673

DEVICE: PERIPHERAL ARTERIAL TONOMETER-PAT 1000RD DEVICE
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

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

510(k) NO: K003293
PHONE NO : 716-691-0010

DEVICE: EXCITE DSC
SE DECISION MADE: 06-FEB-2001
510(k) STATEMENT

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

510(k) NO: K010250
PHONE NO : 716-691-0010

DEVICE: TETRIC CERAM HB
SE DECISION MADE: 28-FEB-2001
510(k) STATEMENT

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

510(k) NO: K003829
PHONE NO : 305-418-2320

DEVICE: TOTAL BILIRUBIN
SE DECISION MADE: 12-FEB-2001
510(k) STATEMENT

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

510(k) NO: K003912
PHONE NO : 305-418-2320

DEVICE: PHOSPHORUS REAGENT
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

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

510(k) NO: K010044
PHONE NO : 203-265-7397

DEVICE: COSMIC
SE DECISION MADE: 09-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

JK GLOVES SDN. BHD.
ATTN: TAI SAI LEONG
LOT 26738 & 26740-K8 & P2
JALAN TEE TECK SA
SENAI, JOHOR,

510(k) NO: K010231
PHONE NO : 607 598 2568

DEVICE: JK GLOVES PRE-POWDERED LATEX EXAMINATION GLOVE
SE DECISION MADE: 09-FEB-2001

510(k) STATEMENT

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KARL STORZ ENDOSCOPY
ATTN: JENNIFER S PORTUGAL
600 CORPORATE POINTE
CULVER CITY, CA 90230-7600

510(k) NO: K004037
PHONE NO : 800-421-0837

DEVICE: X-RAY SYSTEM XR-MX
SE DECISION MADE: 02-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

KARL STORZ LITHOTRIPSY-AMERICA, IN510(k) NO: K010340
RY AND UPPER URETERAL CALCULI
ATTN: MARIKA ANDERSON
600 CORPORATE POINTE
CULVER CITY, CA 90230

PHONE NO : 310-338-8100

DEVICE: MODULITH LITHOTRIPSY, MODEL SLX FOR THE FRAGMENTATION OF URINA
SE DECISION MADE: 13-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

KINAMED, INC.
ATTN: JOEL SLOMOFF
9229 CRANFORD DRIVE
POTOMAC, MD 20854

510(k) NO: K003347
PHONE NO : 301-983-1707

DEVICE: ORTHOPILOT
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

KYPHON INC.
ABLE BONE TAMP, SIZE 15/3, MODEL K02A
ATTN: KAREN TALMADGE
1350 BORDEAUX DRIVE
SUNNYVALE, CA 94089

510(k) NO: K010246
PHONE NO : 408-548-6500

DEVICE: KYPHX INFLATABLE BONE TAMP, SIZE 20/3,MODEL K01A, KYPHX INFLAI
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

LHASA MEDICAL, INC.
ATTN: KYUNG P RIIHIMAKI
234 LIBBEY PARKWAY
WEYMOUTH, MA 02189

510(k) NO: K003760
PHONE NO : 781-340-1070

DEVICE: TAI-CHI ACUPUNCTURE NEEDLES
SE DECISION MADE: 06-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

LIFEMED OF CALIFORNIA
ATTN: PATRICIA BRINKER
1216 S. ALLEC ST.
ANAHEIM, CA 92805

510(k) NO: K001329
PHONE NO : 310-638-6167

DEVICE: INTRAVASCULAR IV SET, IV SET WITH BURETTE, EXTENSION SET
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

LXN CORP.
ATTN: SANDRA F SELVAGGI
6325 LUSK BLVD.
SAN DIEGO, CA 92121

510(k) NO: K002688
PHONE NO : 858-320-4434

DEVICE: PERSONAL GLUCOSE CONTROL CHARTING SYSTEM
SE DECISION MADE: 01-FEB-2001
510(k) STATEMENT

MAEDA TOYOKICHI SHOTEN
ATTN: E.J. SMITH
P.O. BOX 4341
CROFTON, MD 21114

510(k) NO: K000581
PHONE NO : 410-451-0639

DEVICE: MAEDA NEW NEEDLE DISPOSABLE
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MARCONI MEDICAL SYSTEMS
ATTN: RONALD J MARTONE
595 MINER RD.
HIGHLAND HEIGHTS, OH 44143

510(k) NO: K003437
PHONE NO : 440-483-7651

DEVICE: ODYSSEY IX, MODEL 211320
SE DECISION MADE: 02-FEB-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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MARCONI MEDICAL SYSTEMS
ATTN: DUANE PRASCHAN
595 MINER RD.
HIGHLAND HEIGHTS, OH 44143

510(k) NO: K003853
PHONE NO : 440-483-5743

DEVICE: INFINION 1.5T MR IMAGING SYSTEM, MODEL MRI 100
SE DECISION MADE: 13-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MATECH, INC.
ATTN: PAUL L SAXTON
13000 SAN FERNANDO RD.
SYLMAR, CA 91342

510(k) NO: K010069
PHONE NO : 818-367-2472

DEVICE: DURABOND NON-PRECIOUS CERAMIC ALLOY
SE DECISION MADE: 15-FEB-2001
510(k) STATEMENT

MAXXIM MEDICAL
)
ATTN: WUNAN HUANG
308 CHURCH ST.
HONEA PATH, SC 29654

510(k) NO: K010297
PHONE NO : 864-369-7391

DEVICE: SENSICARE SYNTHETIC POWDER FREE SURGICAL GLOVES (POLY ISOPRENE)
SE DECISION MADE: 16-FEB-2001
510(k) STATEMENT

MED-LOGICS, INC.
ATTN: GARY MOCNIK
30001 GOLDEN LANTERN #334
LAGUNA NIGUEL, CA 92677

510(k) NO: K002515
PHONE NO : 949-363-2953

DEVICE: MEDLOGICS ML 4000, MODEL 4000
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

MEDGE PLATFORMS, INC
ATTN: GUSTAVO EDUARDO ABELLA
90 PARK AVENUE
17TH FLOOR
NEW YORK, NY 10016-1301

510(k) NO: K003672
PHONE NO : 212-808-4848

DEVICE: MEDGE PLATFORMS SONOCUBIC 3D ULTRASOUND SOFTWARE
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDI-TECH INIL. CORP.
ATTN: HERBERT A PERRY
26 COURT ST.
BROOKLYN, NY 11242

510(k) NO: K002666
PHONE NO : 718-875-4535

DEVICE: DIAMOND ALCE VERA, STERILE
SE DECISION MADE: 27-FEB-2001
510(k) STATEMENT

MEDICA CORP.
ATTN: PHOIOS MAKRIS
14 DEANGELO DR.
BEDFORD, MA 01730

510(k) NO: K002407
PHONE NO : 781-275-4892

DEVICE: EASYELECTROLYTE NA/K/LI ANALYZER & RAPIDLYTE NA/K/LI ANALYZER
SE DECISION MADE: 02-FEB-2001
510(k) STATEMENT

MEDICAL ANALYSIS SYSTEMS, INC.
TI-PACK
ATTN: DARWIN RICHARDSON
5300 ADOLFO RD.
CAMARILLO, CA 93012

510(k) NO: K010111
PHONE NO : 800-582-3095

DEVICE: CARDIOIMMUNE TL CARDIAC MARKER CONTROL LEVELS 1, 2, 3, AND MUL
SE DECISION MADE: 28-FEB-2001
510(k) STATEMENT

MEDICAL COMPONENTS, INC.
ATTN: FLORENCE A CAIKOSKI
1499 DELP DR.
HARLEYSVILLE, PA 19438

510(k) NO: K010021
PHONE NO : 215-256-4201

DEVICE: MEDCOMP QUAD LUMEN, 8.5F X 20CM, MODEL MC4L-8S
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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MEDICAL DEVICE CONSULTANTS, INC. 510(k) NO: K002699
ATTN: MARY MCNAMARA-CULLIVANE PHONE NO : 508-643-0434
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760

DEVICE: PARIETEX COMPOSITE (PCO) MESH
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDICAL DEVICES, INC. 510(k) NO: K002280
ATTN: WARREN R WALTERS PHONE NO : 515-244-1212
2500 BELL AVENUE
DES MOINES, IA 50321

DEVICE: PAD PRO PEDIATRIC ELECTRODE, MODEL PAD PRO 2602
SE DECISION MADE: 05-FEB-2001
510(k) STATEMENT

MEDICAL ILLUMINATION INTERNATIONAL 510(k) NO: K003489
GERY LIGHT; NEXT GENERATION SPOTLIGHT; NEXT GENERATION M8
ATTN: DAVID GLOVER PHONE NO : 818-899-2888
547 LIBRARY ST.
SAN FERNANDO, CA 91340

DEVICE: NEXT GENERAL M20 SURGICAL LIGHT; NEXT GENERATION M16 MINOR SUR
SE DECISION MADE: 02-FEB-2001
510(k) STATEMENT

MEDICAL METRICS, INC. 510(k) NO: K010187
ATTN: ANN TUNSTALL PHONE NO : 301-652-6110
4600 NORTH PARK AVE.
SUITE 100
CHEVY CHASE, MD 20815-4518

DEVICE: KIMAX, MODEL 1024
SE DECISION MADE: 14-FEB-2001

510(k) SUMMARY AVAILABLE FROM FDA

MEDICOTEST A/S
ATTN: EMALEE G MURPHY
1900 K STREET N.W.
WASHINGTON, DC 20006-1108

510(k) NO: K002079
PHONE NO : 202-496-7255

DEVICE: MULTI-FUNCTION DEFIBRILLATION ELECTRODE
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

MEDISONIC U.S.A., INC.
ATTN: SANDRA WILLIAMSON
1301 GOSHEN PARKWAY
WEST CHESTER, PA 19380

510(k) NO: K003699
PHONE NO : 610-647-9700

DEVICE: MEDIVISION IGS SYSTEM
SE DECISION MADE: 27-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDITHERM INC.
ATTN: PETER LEANDE
7407 DOVER LANE
PARKLAND, FL 33067

510(k) NO: K003332
PHONE NO : 954-575-1076

DEVICE: MEDITHERM MED2000
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

MEDLINE INDUSTRIES, INC.
ES
ATTN: LARA N SIMMONS
ONE MEDLINE PL.
MUNDELEIN, IL 60060-4486

510(k) NO: K003755
PHONE NO : 847-949-2639

DEVICE: MEDLINE BLOCKADE OR RESISTAT SURGICAL GOWNS AND SURGGICAL DRAP
SE DECISION MADE: 16-FEB-2001
510(k) STATEMENT

MEDTOX DIAGNOSTICS, INC.
ATTN: MICHAEL TURANCHIK
1238 ANTHONY RD.
BURLINGTON, NC 27215

510(k) NO: K010138
PHONE NO : 336-226-6311

DEVICE: PROFILE II ER
SE DECISION MADE: 14-FEB-2001
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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MEDTRONIC CARDIAC SURGICAL PRODUCTS 510(k) NO: K000776
ATTN: JAMES BALUN PHONE NO : 616-643-5283
620 WATSON S.W.
GRAND RAPIDS, MI 49504

DEVICE: MEDTRONIC DLP ARTERIAL CANNULAE WITH 3D TIP
SE DECISION MADE: 07-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC FUNCTIONAL DIAGNOSTICS A510(k) NO: K010130
43S0103
ATTN: TOVE KJAER PHONE NO : 454 457 9000
16-18 TONSEBAKKEN
SKOVLUNDE,

DEVICE: POLYGRAM 98 ESOPHAGEAL MANOMETRY TESTING APPLICATION, MODEL 90
SE DECISION MADE: 07-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC PS MEDICAL S 510(k) NO: K003914
ATTN: JANET MCAULEY PHONE NO : 805-968-1546
125 CREMONA DR.
GOLETA, CA 93117

DEVICE: MEDTRONIC PS MEDICAL NEUROOPEN ENDOSCOPE AND OPTICAL ACCESSORIES
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK 510(k) NO: K003718
ATTN: RICHARD W TREHARNE PHONE NO : 901-344-0807
1800 PYRAMID PLACE
MEMPHIS, TN 38132

DEVICE: TITANIUM CEMENT RESTRICTOR (TCR)
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK 510(k) NO: K010249
ATTN: RICHARD W TREHARNE PHONE NO : 901-396-3133
1800 PYRAMID PLACE
MEMPHIS, TN 38132

DEVICE: CD HORIZON SPINAL SYSTEM
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC, INC. 510(k) NO: K003535
ATTN: KAREN CLEMENT PHONE NO : 763-514-9933
4000 LEXINGTON AVE., NORTH
SHOREVIEW, MN 55126-2893

DEVICE: STYLET KIT, MODELS 6254,6282,6293
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC, INC. 510(k) NO: K003667
ATTN: STACEY P WESSMAN PHONE NO : 763-514-9840
7000 CENTRAL AVENUE N.E.
MINNEAPOLIS, MN 55432-3576

DEVICE: REVEAL PLUS INSERTABLE LOOP RECORDER
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

METRON MEDICAL AUSTRALIA P/L 510(k) NO: K003260
ATTN: ROB HOPKINS PHONE NO : 039 775 1234
57 ASTER AVE.
CARRUM DOWNS, VICTORIA,

DEVICE: VECTOR SURGE 4 INTERFERENTIAL THERAPY UNIT MODEL VS 460
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

METRON MEDICAL AUSTRALIA P/L 510(k) NO: K010102
ATTN: ROB HOPKINS PHONE NO : 613 977 51234
57 ASTER AVE.
CARRUM DOWNS, VICTORIA,

DEVICE: SONIC MODEL SO-300
SE DECISION MADE: 09-FEB-2001
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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MICRO THERAPEUTICS, INC. ATTN: EBEN GORDEN 2 GOODYEAR IRVINE, CA 92618	510(k) NO: K010004 PHONE NO : 949-837-3700	DEVICE: FLOWRIDER FLOW DIRECTED MICRO CATHETER, MODEL 105-5065 SE DECISION MADE: 13-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
MICRO-MEDICAL DEVICES, INC. 0 SERIES AND 2.7-5.0MM MODEL MMD-4700 SERIES ATTN: GEORGE COLEMAN 11000 CEDAR AVENUE SUITE 445 CLEVELAND, OH 44106	510(k) NO: K003695 PHONE NO : 216-229-8332	DEVICE: MICROSCOPE-STAINLESS STEEL/FIBER OPTIC: .5-2.6MM MODEL MMD 450 SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
MITEK PRODUCTS ATTN: CAROL CHAOUI 249 VANDERBILT AVE. NORWOOD, MA 02062	510(k) NO: K002406 PHONE NO : 781-251-2700	DEVICE: MITEK 2GII MENISCAL REPAIR SYSTEM SE DECISION MADE: 15-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
MRI DEVICES CORP. ATTN: THOMAS SCHUBERT 1515 PARAMOUNT DRIVE WAUKESHA, WI 53186	510(k) NO: K003655 PHONE NO : 262-524-1402	DEVICE: PHS-63 PEDIATRIC HEAD AND SPINE ARRAY COIL SE DECISION MADE: 02-FEB-2001 510(k) STATEMENT
MRI DEVICES CORP. ATTN: THOMAS SCHUBERT 1515 PARAMOUNT DRIVE WAUKESHA, WI 53186	510(k) NO: K010140 PHONE NO : 262-524-1402	DEVICE: HRH-127 HEAD ARRAY COIL SE DECISION MADE: 22-FEB-2001 510(k) STATEMENT
NEUROSOFT, INC. ATTN: DAVID B JONES 5700 CROMO DRIVE SUITE 100 EL PASO, TX 79912	510(k) NO: K001781 PHONE NO : 915-845-5600	DEVICE: CURRY MULTIMODAL NEUROIMAGING SOFTWARE SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
NEW ENGLAND MEDICAL CORP. 18 ATTN: STEVEN FODOR 2274 ALBANY POST RD. WALDEN, NY 12586	510(k) NO: K002042 PHONE NO : 845-778-4200	DEVICE: TRUCONE ROTATIONAL CONE BIOPSY INSTRUMENT, MODEL 231812 - 2330 SE DECISION MADE: 01-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
NIHON KOHDEN AMERICA, INC. ATTN: BONNIE BISHOP 90 ICON STREET FOOTHILL RANCH, CA 92610	510(k) NO: K002068 PHONE NO : 949-580-1555	DEVICE: CRG-9200A SE DECISION MADE: 08-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
NORTH AMERICAN MEDICAL PRODUCTS, ATTN: ARTHUR GIANAKOS 3 WALKER WAY ALBANY, NY 12205	510(k) NO: K001965 PHONE NO : 518-218-0402	DEVICE: SAFE-POINT VAC, SAFE-POINT M-D BLOOD COLLECTION SYSTEMS SE DECISION MADE: 02-FEB-2001 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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NOVARTIS NUTRITION CORP.
ATTN: SHARON MARTIN
5320 WEST 23RD STREET
PO BOX 370
MINNEAPOLIS, MN 55440

510(k) NO: K001916
PHONE NO : 612-591-2976

DEVICE: COMPAT REPLACEMENT GASTROSTOMY TUBE KIT, MODEL 0974XX
SE DECISION MADE: 16-FEB-2001

510(k) SUMMARY AVAILABLE FROM FDA

NUCLETRON CORPORATION
ATTN: ROBERT APPLEBAUM
7080 COLUMBIA GATEWAY DRIVE
COLUMBIA, MD 21046

510(k) NO: K002429
PHONE NO : 410-312-4103

DEVICE: SELECT SEED I-125
SE DECISION MADE: 02-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

OCU-EASE OPTICAL PRODUCTS, INC.
UFILCON) SOFT CONTACT LENSES FOR DAILY WEAR
ATTN: CHARLES R VERMETTE
629 TENNENT AVE
PINOLE, CA 94564

510(k) NO: K003996
PHONE NO : 800-521-8984

DEVICE: OCU-FLEX-53 THIN ZONE TORIC AND THIN ZONE TORIC ASPHERICAL (OC
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

OCU-EASE OPTICAL PRODUCTS, INC.
OKIFILCON B) SOFT CONTACT LENSES FOR DAILY WEAR (LATHE-CUT
ATTN: CHARLES R VERMETTE
629 TENNENT AVE
PINOLE, CA 94564

510(k) NO: K004000
PHONE NO : 800-521-8984

DEVICE: OCU-FLEX-49 THIN ZONE TORIC AND THIN ZONE TORIC ASPHERICAL (HI
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

OLYMPUS AMERICA, INC.
ATTN: LAURA STORMS-TYLER
TWO CORPORATE CENTER DR.
MELVILLE, NY 11747-3157

510(k) NO: K001744
PHONE NO : 631-844-5688

DEVICE: OLYMPUS ENDOSCOPIC LIGATION DEVICE
SE DECISION MADE: 27-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ONUX MEDICAL, INC.
ATTN: GREGORY E SANCOFF
5 MERRILL DR.
HAMPTON, NH 03842

510(k) NO: K003522
PHONE NO : 603-929-6200

DEVICE: SALUTE
SE DECISION MADE: 13-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

OPTOVENT AB
SE OKIMETRY MODULE)
ATTN: CLAES RYMOND
1350 15TH STREET, SUITE 4H
FORT LEE, NJ 07024

510(k) NO: K003704
PHONE NO : 201-224-3688

DEVICE: OPTOVENT RESPONS, OPTOVENT RENEE (OPTOVENT RESPONS WITHOUT PUL
SE DECISION MADE: 05-FEB-2001
510(k) STATEMENT

ORTEK THERAPEUTICS, INC.
ATTN: JULES T MITCHEL
305 MADISON AVENUE
SUITE 2501
NEW YORK, NY 10165

510(k) NO: K003482
PHONE NO : 212-681-2100

DEVICE: PROCLUDE-SENSITIVE
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

PAN PROBE, INC.
ATTN: ALICE H YU
8515 ARJONS DR., SUITE A
SAN DIEGO, CA 92126

510(k) NO: K010001
PHONE NO : 858-689-9936

DEVICE: LIVESURE THC SCREEN TEST
SE DECISION MADE: 05-FEB-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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PARAGON VISION SCIENCES ATTN: WILLIAM E MEYERS 947 EAST IMPALA AVE. MESA, AZ 85204	510(k) NO: K010109 PHONE NO : 480-507-7606	DEVICE: FLUOROPERM 151-OK, PARAGON HDS 100-OK SE DECISION MADE: 28-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
PARE SURGICAL, INC. ATTN: RICHARD P FLEENOR 7332 SOUTH ALTON WAY, UNIT H ENGLEWOOD, CO 80112	510(k) NO: K003102 PHONE NO : 303-689-0187	DEVICE: PARE ENDOSCOPIC SUTURING SYSTEM SE DECISION MADE: 27-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
PERUSAHAAN GETAH ASAS SDN BHD LABELING CLAIM (200 MICROGRAMSPER OR LESS) ATTN: TAN KONG CHANG LOT 754, JALAN HAJI SIRAT SELANGOR,	510(k) NO: K003737 PHONE NO : 603 391 1949	DEVICE: POWDERED LATEX PATIENT EXAMINATION GLOVE WITH PROTEIN CONTENT SE DECISION MADE: 01-FEB-2001 510(k) STATEMENT
PHAMATECH ATTN: CARL A MONGIOVI 9520 PADGETT STREET #101 SAN DIEGO, CA 92126	510(k) NO: K003858 PHONE NO : 858-635-5840	DEVICE: MODIFICATION TO AT HOME DRUG TEST, MODELS 9150, 9068, AND 9175 SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
PIONEER LABORATORIES, INC. ATTN: AMY H MOMMAERTS 375 RIVER PARK CIRCLE MARQUETTE, MI 49855-0627	510(k) NO: K003496 PHONE NO : 906-226-9909	DEVICE: CANNULATED SCREW SYSTEM SE DECISION MADE: 08-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
POLYMER TECHNOLOGY ATTN: NANCY ABRAHAM 1400 N GOODMAN STREET ROCHESTER, NY 14603-0450	510(k) NO: K003932 PHONE NO : 716-338-8227	DEVICE: BOSTON EO (ENFLUFOCON B) CONTACT LENS FOR ORTHOKERATOLOGY SE DECISION MADE: 16-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
POLYMER TECHNOLOGY GY ATTN: NANCY ABRAHAM 1400 N GOODMAN STREET ROCHESTER, NY 14603-0450	510(k) NO: K003933 PHONE NO : 716-338-8227	DEVICE: BOSTON EQUALENS II (OPRIFOCON A) CONTACT LENS FOR ORTHOKERATOLOGY SE DECISION MADE: 16-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
PROCIER & GAMBLE CO. ATTN: KATHLEEN C BLIEZNER 6110 CENTER HILL AVENUE CINCINNATI, OH 45224	510(k) NO: K003843 PHONE NO : 513-634-3265	DEVICE: ENVIVE MINIFORMS SE DECISION MADE: 08-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
PWA INDUSTRIES SDN. BHD. GLOVES ATTN: K. KARUNAKARAN LOT 93, SEMAMBU INDUST. ESTATE KUANJAN, PAHANG,	510(k) NO: K010077 PHONE NO : 001 609 5670835	DEVICE: HEALTH-PLUS, SANITEX, RELIANCE POWDER-FREE NITRILE EXAMINATION SE DECISION MADE: 28-FEB-2001 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDPH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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RECLINER CARE, INC.
ATTN: MARK D BROWN
122 AVENIDA DEL SOL
SAN ANTONIO, TX 78232

510(k) NO: K010194
PHONE NO : 210-496-0915

DEVICE: COMFOR-CLINER
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

RESPIRONICS, INC.
ATTN: DAVID J VANELLA
1001 MURRY RIDGE LANE
MURRYSVILLE, PA 15668

510(k) NO: K003499
PHONE NO : 724-733-5866

DEVICE: REMVIEW SLEEP RECORDER, MODEL 320
SE DECISION MADE: 09-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
ATTN: JENNIFER TRIBBEIT
9115 HAGUE RD.
INDIANAPOLIS, IN 46250-0457

510(k) NO: K003865
PHONE NO : 317-576-3742

DEVICE: COBAS INTEGRA AMPHETAMINES
SE DECISION MADE: 28-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
ATTN: HELEN T TORNEY
9115 HAGUE RD.
INDIANAPOLIS, IN 46250-0457

510(k) NO: K010237
PHONE NO : 317-576-7643

DEVICE: ELECSYS HCG+B CALCHECK
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ROSSMAX INTERNATIONAL LTD.
ATTN: MICHAEL YEH
12F, NO. 189, KANG CHIEN RD.
TAIPEI,

510(k) NO: K010190
PHONE NO : 011 886 226597888

DEVICE: WRISTWATCH BLOOD PRESSURE MONITOR, MODEL A43
SE DECISION MADE: 08-FEB-2001
510(k) STATEMENT

RUSCH INVL.
ATTN: KARENANN J BROZOWSKI
50 PLANTATION DRIVE
JAFFERY, NH 03452

510(k) NO: K010068
PHONE NO : 603-532-7706

DEVICE: RUSCH POLYFLEX STENT FOR THE ESOPHAGUS WITH INTRODUCER SYSTEM
SE DECISION MADE: 08-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

S & C POLYMER GMEH
ATTN: JURGEN ENGELBRECHT
ROBERT-BOSCH-STRASSE 5
ELMSHORN,

510(k) NO: K010012
PHONE NO : 004 941 214830

DEVICE: LC PROVIFILL
SE DECISION MADE: 14-FEB-2001
510(k) STATEMENT

S.A.A.T., LTD.
ATTN: SHOSHANA FRIEDMAN
117 AHUZAH ST.
PUSH-MED LTD
RA'ANANNA,

510(k) NO: K002712
PHONE NO : 972 977 18130

DEVICE: THERMO TEK IR FOREHEAD THERMOMETER, MODEL 718F
SE DECISION MADE: 08-FEB-2001

510(k) SUMMARY AVAILABLE FROM FDA

SAAT LTD.
ATTN: E. J SMITH
1468 HARWELL AVENUE
CROFTON,, MD 21114

510(k) NO: K010502
PHONE NO : 410-451-0639

DEVICE: MODEL THERMO TEK QUICKCARE
SE DECISION MADE: 27-FEB-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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SGMP CO., LTD. THOUT GRAPE SCENT WITH PROTEIN LABELING (200 MICROGRAMS OR ATTN: JANNA P TUCKER 198 AVENUE DE LA D'EMERALD SPARKS, NV 89434	510(k) NO: K010095 PHONE NO : 775-342-2612	DEVICE: NONSTERILE POWDERED PURPLE LATEX EXAMINATION GLOVES, WITH & WI SE DECISION MADE: 09-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SHANGHAI CHINASTAR CORP. ATTN: LEE HUNG TE CHIH NO. 283, CHE KING ROAD CHE DUN ZHEN, SONG JIANG COUNTY SHANGHAI,	510(k) NO: K010247 PHONE NO : 886 227 138677	DEVICE: SHANGHAI CHINASTAR POWER-FREE BLUE NITRIL EXAMINATION GLOVES SE DECISION MADE: 06-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SHIMADZU MEDICAL SYSTEMS 200 ATTN: MASAOKI SHIBATA 20101 SOUTH VERMONT AVE. TORRANCE, CA 90502	510(k) NO: K003514 PHONE NO : 310-217-8855	DEVICE: ECHO VIEW/SHIMASONIC DIAGNOSTIC ULTRASOUND SYSTEM, MODEL SDU-2 SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SHIMADZU MEDICAL SYSTEMS 200 ATTN: MASAOKI SHIBATA 20101 SOUTH VERMONT AVE. TORRANCE, CA 90502	510(k) NO: K003515 PHONE NO : 310-217-8855	DEVICE: ECHO VIEW/SHIMASONIC DIAGNOSTIC ULTRASOUND SYSTEM, MODEL SDU-1 SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SIE-MED, INC. ATTN: CHARLES H KYPER 11902 SIMPSON ROAD CLARKSVILLE, MD 21029	510(k) NO: K003130 PHONE NO : 301-776-3546	DEVICE: REGUTHERM 952 THERMOGRAPHIC SYSTEM SE DECISION MADE: 16-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SIEMENS MEDICAL SYSTEMS, INC. ATTN: PRAVEEN NADKARNI 186 WOOD AVENUE SOUTH ISELIN, NJ 08830	510(k) NO: K003945 PHONE NO : 732-321-4950	DEVICE: OPDIMA SE DECISION MADE: 02-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SIEMENS MEDICAL SYSTEMS, INC. II OCI/SPECT ATTN: RONALD NOLTE 2501 NORTH BARRINGTON RD. HOFFMAN ESTATES, IL 60195-7372	510(k) NO: K010137 PHONE NO : 847-304-7504	DEVICE: ORBITER II OCI/SPECT SE DECISION MADE: 13-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	ORBITER
SIMS PORTEX, INC. ATTN: TIMOTHY J TALCOTT 10 BOWMAN DR. KEENE, NH 03431	510(k) NO: K002201 PHONE NO : 603-352-3812	DEVICE: ELECTROSTATIC HYDROPHOBIC BREATHING FILTER SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA	
SMITH & NEPHEW, INC. ATTN: DAVID HENLEY 1450 E. BROOKS ROAD MEMPHIS, TN 38116	510(k) NO: K003566 PHONE NO : 901-399-6487	DEVICE: OOFIELD ECCENTRIC AND LATERAL OFFSET HUMERAL HEADS SE DECISION MADE: 14-FEB-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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SMITH & NEPHEW, INC.
ATTN: MARK KIERAS
160 DASCOMB RD.
ANDOVER, MA 01810

510(k) NO: K003572
PHONE NO : 978-749-1121

DEVICE: DYONICS CONTROL RF SYSTEM
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SMITH & NEPHEW, INC.
ATTN: WILLIAM MCCALLUM
160 DASCOMB RD.
ANDOVER, MA 01810

510(k) NO: K003599
PHONE NO : 508-261-3620

DEVICE: SMITH & NEPHEW SUTURE ANCHOR
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SMITH & NEPHEW, INC.
NICS AUTOCLAVABLE CAMERA COUPLER MODEL 7207905
ATTN: JANICE HASELTON
160 DASCOMB RD.
ANDOVER, MA 01810

510(k) NO: K003710
PHONE NO : 978-749-1494

DEVICE: DYONICS VISION 337 AUTOCLAVABLE CAMERA HEAD MODEL 7209048; DYC
SE DECISION MADE: 02-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SONOSITE, INC.
ATTN: MICHAEL A HOFFMAN
21919 30TH DRIVE SE.
BOIHILL, WA 98021-3904

510(k) NO: K010374
PHONE NO : 425-951-1297

DEVICE: SONOSITE HAND-CARRIED ULTRASOUND SYSTEM
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SPECIALTY ULTRAVISION, INC.
S FOR DAILY WEAR, SPECIALTY 55 UV MULTIFOCAL (METHAFILCON)
ATTN: GAROLD L EDWARDS
307 ORCHARD CITY DRIVE
SUITE 100
CAMPELL, CA 95008

510(k) NO: K003526
PHONE NO : 408-341-0700

DEVICE: SPECIALTY 55 UV (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS
SE DECISION MADE: 12-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SPECIALTY ULTRAVISION, INC.
FOR DAILY WEAR; SPECIALTY 56 UV TORIC (HEFILCON C) SOFT
ATTN: DEBBIE MCINTIRE
307 ORCHARD CITY DRIVE
SUITE 100
CAMPELL, CA 95008

510(k) NO: K003789
PHONE NO : 408-341-0700

DEVICE: SPECIALTY 56 UV (HEFILCON C) SOFT (HYDROPHILIC) CONTACT LENS
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ST. FRANCIS MEDICAL EQUIPMENT CO.,
5
ATTN: FRANCIS HONG
P.O. BOX 129
SHIEN CHUANG 24299
TAIPEI SHIEN, TAIWAN, R.O.C.,

510(k) NO: K003423
PHONE NO : 886 222 781555

DEVICE: ST. FRANCIS OPERATING THEATRE LAMP, MODELS OLH01-125 AND LC-05
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

STELKAST CO.
ATTN: DONALD A STEVENS
800 VINIAL ST. #210
PITTSBURGH, PA 15212

510(k) NO: K010241
PHONE NO : 412-322-8280

DEVICE: PROTRACT PRESS FIT HIP STEM-HA COATED
SE DECISION MADE: 08-FEB-2001
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
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STELKAST CO.
ATTN: DONALD A STEVENS
800 VINAL ST. #210
PITTSBURGH, PA 15212

510(k) NO: K010282
PHONE NO : 412-322-8280

DEVICE: LATERAL OFFSET PROTRACT PRESS FIT HIP STEM
SE DECISION MADE: 09-FEB-2001
510(k) STATEMENT

STERINC
0073
ATTN: GARY FRUGARD
3520 W. WARNER AVENUE
SANTA ANITA, CA 92704

510(k) NO: K002912
PHONE NO : 949-493-5829

DEVICE: VAGINAL PORT, NON-STERILE / 600065, VAGINAL PORT, STERILE / 60
SE DECISION MADE: 21-FEB-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: K003533
PHONE NO : 303-660-4201

DEVICE: CROSS-CHECKS LF, MODEL CI 119/S & CI 119/L
SE DECISION MADE: 07-FEB-2001
510(k) STATEMENT

STRYKER CORP.
ATTN: MICHAEL BAYCURA
2590 WALSH AVE.
SANTA CLARA, CA 95051

510(k) NO: K003792
PHONE NO : 408-567-9100

DEVICE: STRYKER HEATED INSUFFLATOR TUBE SET
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SULZER ORTHOPEDICS, INC.
ATTN: MITCHELL A DHORTY
9900 SPECTRUM DR.
AUSTIN, TX 78717

510(k) NO: K003801
PHONE NO : 512-432-9202

DEVICE: ANATOMICAL PRESS-FIT HUMERAL STEM
SE DECISION MADE: 28-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SUPERMAX GLOVE MANUFACTURING SDN B
ATTN: STANLEY THAI
47000 SUNGAI BULOH
SELANGOR,

510(k) NO: K010198
PHONE NO : 603 615 72328

DEVICE: STERILE POWDERED LATEX SURGEON GLOVES
SE DECISION MADE: 23-FEB-2001
510(k) STATEMENT

SURGI-VISION, INC.
ATTN: NANCY E TALOR
9250 RUMSEY RD., SUITE 100
COLUMBIA, MD 21045

510(k) NO: K003436
PHONE NO : 410-730-8998

DEVICE: SURGI-VISION GUIDEWIRE COIL
SE DECISION MADE: 02-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SURVIVALINK CORP.
ATTN: SEW-WAH TAY
5420 FELLER RD.
MINNEAPOLIS, MN 55343

510(k) NO: K010214
PHONE NO : 952-939-4181

DEVICE: FIRSTSAVE BIPHASIC MODEL #9200 AND 9210
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYBRON DENTAL SPECIALTIES, INC.
ATTN: COLLEEN BOSELL
1717 WEST COLLINS AVENUE
ORANGE, CA 92867

510(k) NO: K003640
PHONE NO : 714-516-7484

DEVICE: MINIENDO III
SE DECISION MADE: 22-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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SYBRON DENTAL SPECIALTIES, INC. 510(k) NO: K003650
ATTN: COLLEEN BOSWELL PHONE NO : 714-516-7484
1717 WEST COLLINS AVENUE
ORANGE, CA 92667

DEVICE: PERMLASTIC 3
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYNERGENT BIOCHEM INC.-CLINICAL 510(k) NO: K010030
ATTN: JAMES F GODFREY PHONE NO : 800-585-8580
12038 CENTRAILIA AVE
SUITE C
HAWAIIAN GARDENS, CA 90716

DEVICE: LIQUISPX HDL/LDL LIQUID CHOLESTEROL CALIBRATOR
SE DECISION MADE: 14-FEB-2001

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA) 510(k) NO: K003700
ATTN: THOMAS M MAGUIRE PHONE NO : 610-647-9700
1690 RUSSELL RD.
PAOLI, PA 19301

DEVICE: SYNTHES HAMSTRING LOOP
SE DECISION MADE: 20-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA) 510(k) NO: K003743
ATTN: ANGELA J SILVESTRI PHONE NO : 610-647-9700
1690 RUSSELL ROAD
PAOLI, PA 19301

DEVICE: SYNTHES MODIFIED BIORESORBABLE SUTURE ANCHOR SYSTEM
SE DECISION MADE: 09-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA) 510(k) NO: K003786
ATTN: THOMAS M MAGUIRE PHONE NO : 610-647-9700
P.O. BOX 1766
1690 RUSSELL ROAD
PAOLI, PA 19301-1222

DEVICE: SMF RESORBABLE MESHES AND SHEETS
SE DECISION MADE: 27-FEB-2001

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA) 510(k) NO: K010121
ATTN: THOMAS M MAGUIRE PHONE NO : 610-647-9700
1690 RUSSELL RD.
PAOLI, PA 19301

DEVICE: STERILE BUTTON PLATE
SE DECISION MADE: 09-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

TAUT, INC. 510(k) NO: K003703
ATTN: RONALD KENSETH PHONE NO : 630-232-2507
2571 KANEVILLE COURT
GENEVA, IL 60134

DEVICE: TAUT-INSUFFLATION NEEDLE
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

TAUT, INC. 510(k) NO: K010007
ATTN: RONALD KENSETH PHONE NO : 630-232-8005
2571 KANEVILLE COURT
GENEVA, IL 60134

DEVICE: ADAPT LAPAROSCOPIC PORT & ADAPT REDUCER CAP
SE DECISION MADE: 22-FEB-2001
510(k) STATEMENT

TE ME NA S.A.R.L. 510(k) NO: K991259
ATTN: ARTHUR WARD PHONE NO : 813-645-2855
390 SCARLET BLVD
OLDSMAR, FL 34677

DEVICE: TE ME NA EPIDURAL CATHETER
SE DECISION MADE: 21-FEB-2001
510(k) STATEMENT

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TECH-MED SERVICES, INC. ATTN: RICHARD GRAVER 933A MOTOR PARKWAY HAUPPAQUE, NY 11788	510(k) NO: K010094 PHONE NO : 631-582-7320	DEVICE: A & I WHEELCHAIRS SE DECISION MADE: 15-FEB-2001 510(k) STATEMENT
TENS CARE LTD. ATTN: BERNARD J TREMAINE 76, STOCKPORT ROAD TIMPERLRY,	510(k) NO: K003591 PHONE NO : 441 019 804310	DEVICE: TENS CARE, MODEL TENS XL-2 SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
TERRAY CORP. 301-03 ATTN: STEVE WANG 49 JACKSON LANE ARNPRIOR,	510(k) NO: K003629 PHONE NO : 613 623 3310	DEVICE: MTP RESESURFACING JOINT-SMALL/9301-01; MEDIUM/9301-02; LARGE/9 SE DECISION MADE: 22-FEB-2001 510(k) STATEMENT
TERUMO CARDIOVASCULAR SYSTEMS CORP ATTN: GARRY A COURNEY 125 BLUE BALL ROAD ELKTON, MD 21921	510(k) NO: K003604 PHONE NO : 800-283-7866	DEVICE: ADAPTERS WITH X-COATING SE DECISION MADE: 07-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
TERUMO MEDICAL CORPORATION ATTN: YUK-TING LEWIS 125 BLUE BALL ROAD ELKTON, MD 21921	510(k) NO: K003425 PHONE NO : 410-392-7213	DEVICE: CLIRANS E-SERIES HOLLOW FIBER DIALYZERS SE DECISION MADE: 01-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
TERUMO MEDICAL CORPORATION SYRINGE ATTN: BARBARA SMITH 125 BLUE BALL ROAD ELKTON, MD 21921	510(k) NO: K003571 PHONE NO : 410-392-7241	DEVICE: SERONO FOR USE WITH GONAL-F 1200IU MULTI-DOSE ONLY AT 600IU/ML SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
THE BINDING SITE, LTD. ATTN: JAY H GELLER WEST TOWER, SUITE 4000 2425 WEST OLYMPIC BOULEVARD SANTA MONICA, CA 90404	510(k) NO: K003669 PHONE NO : 310-449-1399	DEVICE: KAPPA IMAGE FREELITE KIT SE DECISION MADE: 01-FEB-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: K003671 PHONE NO : 310-449-1399	DEVICE: LAMBDA IMAGE FREELITE KIT SE DECISION MADE: 01-FEB-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: K004019 PHONE NO : 310-449-1399	DEVICE: ANA EIA DIAGNOSTIC TEST KIT SE DECISION MADE: 15-FEB-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: K010148
PHONE NO : 310-449-1399

DEVICE: ENA SCREEN EIA KIT
SE DECISION MADE: 23-FEB-2001

510(k) STATEMENT

THE WESTAIM CORP.
ATTN: STEVEN CHARTIER
1 HAMPTON RD., #302
EXETER, NH 03833-4807

510(k) NO: K002896
PHONE NO : 603-775-7300

DEVICE: ACTICOAT FOAM DRESSING, ALGISITE M CALCIUM ALGINATE DRESSING
SE DECISION MADE: 21-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

TILLOTSON HEALTHCARE CORPORATION
CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)
ATTN: F.W. PERRELLA
360 ROUTE 101
BEDFORD, NH 03110

510(k) NO: K004048
PHONE NO : 603-472-6600

DEVICE: SENSIGRIP LTC POWDER FREE LATEX EXAMINATION GLOVE WITH PROTEIN
SE DECISION MADE: 06-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

TOKUYAMA AMERICA, INC.
ATTN: DANIEL J MANELLI
2000 M STREET (SUITE 700)
WASHINGTON, DC 20036

510(k) NO: K010267
PHONE NO : 202-261-1040

DEVICE: PALFIQUE ESTELITE LV CLEAR
SE DECISION MADE: 27-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

TOMTEC IMAGING SYSTEMS, GMBH
ATTN: FLORIAN EISENBERGER
EDISONSTRASSE 6
UNTERSCHLEISSHEIM,

510(k) NO: K003936
PHONE NO : 011 49 8932175830

DEVICE: PANORAMIC SCAN, PANORAMIC VIEW, WIDAS, WIDE AREA SCANNING
SE DECISION MADE: 14-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

TOTAL WATER TREATMENT SYSTEMS, INC.
ATTN: KENNETH J CLARK
4806 EAST BROADWAY
MADISON, WI 53716

510(k) NO: K002045
PHONE NO : 608-221-2236

DEVICE: WATER PURIFICATION SYSTEM FOR HEMODIALYSIS
SE DECISION MADE: 16-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K003834
PHONE NO : 800-216-9036

DEVICE: SENSITIVE SUSCEPTIBILITY PLATES-ADDITIONAL ANTIMICROBICS
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K003868
PHONE NO : 800-216-9036

DEVICE: SENSITIVE SUSCEPTIBILITY PLATES-ADDITIONAL ANTIMICROBICS
SE DECISION MADE: 27-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

TUTINAUER CO. LTD.
ATTN: MARK YACURA
1776 K STREET N.W.
SUITE 800
WASHINGTON, DC 20006-2365

510(k) NO: K003470
PHONE NO : 202-452-7949

DEVICE: EHS SERIES TABLE TOP AUTOCLAVE, MODELS 2540 AND 3870
SE DECISION MADE: 20-FEB-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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TUTTNAUER USA CO. LTD.
ATTN: MARK M YACURA
1776 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20006-7910

510(k) NO: K993856
PHONE NO : 202-452-7949

DEVICE: TUTTNAUER ELECTRONIC AUTOCLAVE, MODELS E, EA, EK, EKA, EP
SE DECISION MADE: 09-FEB-2001

510(k) SUMMARY AVAILABLE FROM FDA

ULTRADENT PRODUCTS, INC.
ATTN: MARKUS R GEE
505 WEST 10200 SOUTH
SOUTH JORDAN, UT 84065

510(k) NO: K003383
PHONE NO : 800-552-5512

DEVICE: PALMLIGHT
SE DECISION MADE: 06-FEB-2001
510(k) STATEMENT

UROMED CORP.
ATTN: FREDERICK TOBIA
1400 PROVIDENCE HWY.
NORWOOD, MA 02062

510(k) NO: K010098
PHONE NO : 781-762-2080

DEVICE: MODIFICATION TO CAVERMAP SURGICAL AID
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

VARIAN MEDICAL SYSTEMS, INC.
ATTN: LINDA S NASH
3100 HANSEN WAY
PALO ALTO, CA 94304-1129

510(k) NO: K003636
PHONE NO : 650-424-6990

DEVICE: PORTALVISION
SE DECISION MADE: 02-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

VASCULAR ARCHITECTS, INC.
ATTN: JEAN M CAILLOUETTE
1830 BERING DR.
SAN JOSE, CA 95112-4226

510(k) NO: K003719
PHONE NO : 408-392-7437

DEVICE: VASCULAR ARCHITECTS PERISCOPE DEVICE
SE DECISION MADE: 28-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

VIDAMED, INC.
ATTN: TOM MCGAFFIGAN
46107 LANDING PKWY.
FREMONT, CA 94538

510(k) NO: K002583
PHONE NO : 510-492-4930

DEVICE: TUNA (TRANS URETHRA NEEDLE) OFFICE SYSTEM
SE DECISION MADE: 13-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

VISUALIZATION TECHNOLOGY, INC.
ATTN: NORMA LEMAY
200 RESEARCH DR.
WILMINGTON, MA 01887

510(k) NO: K003510
PHONE NO : 978-933-1000

DEVICE: INSTATRAK SYSTEM WITH FLUOROCAT, MODEL IT3500
SE DECISION MADE: 12-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

VIZTEK, INC.
ATTN: JOSIP CERMIN
6491 POWERS AVE.
JACKSONVILLE, FL 32217

510(k) NO: K003607
PHONE NO : 904-733-3656

DEVICE: ONYX-RAD TELEMEDICINE PACS
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

VORTRAN MEDICAL TECHNOLOGY 1, INC.
ATTN: GORDON A WONG
3941 J ST., SUITE 354
SACRAMENTO, CA 95819

510(k) NO: K003684
PHONE NO : 916-733-6870

DEVICE: PERCUSSTIVENEB, MODEL PN-2001
SE DECISION MADE: 23-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

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W & H DENTALWERK BUERMOOS GMBH ATTN: HERBERT TRASCHWANDNER IGNAZ GLASER STR. 53 A-5111 BUERMOOS,	510(k) NO: K002469 PHONE NO : 011 436 27462360	DEVICE: IMPLANIMED SI-95 115 (100-130 V) AND SI-95 230 (220-240 V) SE DECISION MADE: 07-FEB-2001 510(k) STATEMENT
W.L. GORE & ASSOCIATES, INC ATTN: R. LARRY PRATT 3750 WEST KILTIE LN. FLAGSTAFF, AZ 86002-0900	510(k) NO: K010228 PHONE NO : 800-528-1866	DEVICE: GORE-TEX DUALMESH PLUS BIOMATERIAL WITH HOLES SE DECISION MADE: 21-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
WALLAC OY ATTN: GUNNEL LAAKSONEN MUSTIONKATU 6 TURKU,	510(k) NO: K003664 PHONE NO : 358 226 78111	DEVICE: DELFIA NEONATAL IRT KIT, MODEL A005-110 SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
WALLAC OY ATTN: GUNNEL LAAKSONEN MUSTIONKATU 6 TURKU,	510(k) NO: K003668 PHONE NO : 358 226 78111	DEVICE: AUTODELFIA NEONATAL IRT KIT, MODEL B005-112 SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
WALTER LORENZ SURGICAL, INC. ATTN: STEVE HERRINGTON 1520 TRADEPORT DR. JACKSONVILLE, FL 32218	510(k) NO: K002083 PHONE NO : 904-741-4400	DEVICE: LORENZ RESORBABLE DISTRACTOR SYSTEM SE DECISION MADE: 12-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
WANDY RUBBER INDUSTRIAL CO., LTD ATTN: JANIS YANG NO. 22, ALLAY 37, LANE 266 FU TEH I RD. SHI-CHIH, TAIPEI,	510(k) NO: K002219 PHONE NO : 886 269 43184	DEVICE: WANDY SELF-ADHESIVE NEUROSTIMULATION ELECTRODE SE DECISION MADE: 02-FEB-2001 510(k) STATEMENT
WANDY RUBBER INDUSTRIAL CO., LTD ATTN: JANIS YANG NO. 22, ALLAY 37, LANE 266 FU TEH I RD. SHI-CHIH, TAIPEI,	510(k) NO: K002227 PHONE NO : 886 269 43184	DEVICE: WANDY SILICONE CONDUCTIVE RUBBER PAD SE DECISION MADE: 02-FEB-2001 510(k) STATEMENT
WEBB RESEARCH II, INC. ATTN: STEVEN KRUPNICK 1241 CARPENTER STREET PHILADELPHIA, PA 19147	510(k) NO: K003773 PHONE NO : 215-336-5570	DEVICE: CLEAN SCRAPE SE DECISION MADE: 02-FEB-2001 510(k) STATEMENT
WESTAIM BIOMEDICAL, INC. ATTN: STEVE CHARTER ONE HAMPTON RD. SUITE 302 EXETER, NH 03833	510(k) NO: K002466 PHONE NO : 603-775-7300	DEVICE: ACTICOAT COMPOSITE DRESSING SE DECISION MADE: 16-FEB-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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WESTERN SYSTEMS RESEARCH, INC.
ATTN: LINDA DAVIS-O'LEARY
260 S. LOS ROBLES AVE. STE 106
PASADENA, CA 91101

510(k) NO: K010059
PHONE NO : 626-578-7363

DEVICE: ENGPLUS
SE DECISION MADE: 27-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

WRIGHT MEDICAL TECHNOLOGY, INC.
ATTN: EHAB M ESMAIL
5677 AIRLINE RD.
ARLINGTON, TN 38002

510(k) NO: K004032
PHONE NO : 901-867-4732

DEVICE: PERFECTA AND EXTEND
SE DECISION MADE: 15-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ZCV, INC.
ATTN: JING ZHANG
298 FERNWOOD AVE.
EDISON, NJ 08837

510(k) NO: K010099
PHONE NO : 732-225-3800

DEVICE: ZYNERGY Z3K BALLOON GUIDED PACING AND MONITORING CATHETER
SE DECISION MADE: 01-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ZIMMER, INC.
ATTN: KAREN CAIN
P.O. BOX 708
WARSAW, IN 46581-0708

510(k) NO: K003478
PHONE NO : 219-372-4219

DEVICE: TRIOLGY ACETABULAR SYSTEM 46MM LARGE HEAD LINERS, MODEL 6310
SE DECISION MADE: 05-FEB-2001
510(k) SUMMARY AVAILABLE FROM FDA

ZOLL MEDICAL CORP.
ATTN: PAUL DIAS
32 SECOND AVE.
BURLINGTON, MA 01803

510(k) NO: K010257
PHONE NO : 781-229-0020

DEVICE: ZOLL M SERIES
SE DECISION MADE: 28-FEB-2001
510(k) STATEMENT

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TOTAL 510(k)s THIS PERIOD	265
TOTAL WITH SUMMARIES	190
TOTAL WITH STATEMENTS	75