

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-SEP-2001 THROUGH 30-SEP-2001

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3D MED CO., LTD.  
ATTN: CYNTHIA J.M. NOLTE  
49 PLAIN STREET  
NORTH ATTLEBORO, MA 02760

510(k) NO: K012290  
PHONE NO : 919-859-4207

DEVICE: RAPIDIA  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

AARON MEDICAL, INC.  
ATTN: RICHARD KOZLOFF  
7100- 30TH AVENUE NORTH  
ST. PETERSBURG, FL 33710

510(k) NO: K011929  
PHONE NO : 727-384-2323

DEVICE: HANDPIECE SHEATH-MODEL #A910  
SE DECISION MADE: 18-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES  
ATTN: JOHN DEAN  
5440 PATRICK HENRY DR.  
SANITA CLARA, CA 95054

510(k) NO: K012934  
PHONE NO : 408-567-3430

DEVICE: CELL-DYN 3200 SYSTEM WITH ABSOLUTE AND PERCENT RETICULOCYTE  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ACCUIMAGE DIAGNOSTICS CORP.  
ATTN: GARY J ALLSEBROOK  
16303 PANORAMIC WAY  
SAN LEANDRO, CA 94578-1116

510(k) NO: K012106  
PHONE NO : 510-276-2648

DEVICE: ACCUIMAGE SMARTGATE UPGRADE  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ACON LABORATORIES, INC.  
P BENZODIAZEPINES TEST DEVICE  
ATTN: EDWARD TUNG  
4108 SORRENTO VALLEY BLVD.  
SAN DIEGO, CA 92121

510(k) NO: K012300  
PHONE NO : 858-535-2030

DEVICE: ACON BZO ONE STEP BENZODIAZEPINES TEST STRIP; ACON BZO ONE STE  
SE DECISION MADE: 17-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ACRYMED, INC.  
ATTN: BRUCE GIBBINS  
12232 S.W. GARDEN PL.  
PORTLAND, OR 97223

510(k) NO: K012116  
PHONE NO : 503-624-9830

DEVICE: ACRYDERM SILVER ANTIMICROBIAL PERFORATED WOUND DRESSING  
SE DECISION MADE: 12-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ACUSUPPLY, INC.  
SINGLE USE  
ATTN: FERES DAGER  
3801 NE 207TH STREET  
AVENTURA, FL 33180

510(k) NO: K011242  
PHONE NO : 305-932-9413

DEVICE: HUANQIU AND SUPER (TWO BRANDS) STERILE ACUPUNCTURE NEEDLE FOR  
SE DECISION MADE: 11-SEP-2001  
510(k) STATEMENT

ADVANCE MEDICAL DESIGNS, INC.  
ATTN: BILL GILL  
1241 ATLANTA INDUSTRIAL DR.  
MARIETTA, GA 30066

510(k) NO: K012168  
PHONE NO : 770-422-3125

DEVICE: ADVANCE MEDICAL DESIGNS FLUID POUCH  
SE DECISION MADE: 18-SEP-2001  
510(k) STATEMENT

ADVANCED ORTHOPAEDIC SOLUTIONS  
ATTN: GARY SOHNGEN  
333 WEST 6TH ST., SUITE 202  
SAN PEDRO, CA 90731

510(k) NO: K012190  
PHONE NO : 310-831-6787

DEVICE: AOS MODULAR FEMORAL NAIL  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

945-0120

LST106

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

510(k) NO: K012201  
PHONE NO : 619-977-1465

DEVICE: PREMICON NONABSORBABLE PET SURGICAL SUTURE  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

AETIMED, S.P.A.  
ATTN: COLLEEN HITTLE  
7992 CASTLEWAY DRIVE  
INDIANAPOLIS, IN 46250

510(k) NO: K012093  
PHONE NO : 317-849-1916

DEVICE: AETIMED IMAGE PROCESSING SOFTWARE  
SE DECISION MADE: 21-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

AGFA CORP.  
ATTN: T.WHIT ATHEY  
12300 TWINEROCK PKWY, STE 625  
ROCKVILLE, MD 20852

510(k) NO: K012010  
PHONE NO : 301-770-9590

DEVICE: MODIFICATION TO LR 5200 FILM RECORDER  
SE DECISION MADE: 20-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

AGFA-GEVAERT AG  
ATTN: T. WHIT ATHEY  
12300 TWINEROCK PARKWAY  
SUITE 625  
ROCKVILLE, MD 20852

510(k) NO: K013138  
PHONE NO : 301-770-9590

DEVICE: ADC COMPACT PLUS  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K010949  
PHONE NO : 800-235-5941

DEVICE: 2010 PLUS HOLTER FOR WINDOWS  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.  
Y LABELING CLAIM  
ATTN: ERICA SEIHI  
1500 WAUKEGAN RD. BLDG. WM  
MCGAW PARK, IL 60085

510(k) NO: K012149  
PHONE NO : 847-785-3337

DEVICE: POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN, CHEMOTHERAP  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.  
ATTN: SHARON ROBBINS  
1500 WAUKEGAN RD. BLDG. WM  
MCGAW PARK, IL 60085

510(k) NO: K012984  
PHONE NO : 847-785-3311

DEVICE: BREATHABLE IMPERVIOUS GOWNS  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN DIAGNOSTICA, INC.  
ATTN: JOHN B BERRYMAN  
222 RAILROAD AVE.  
GREENWICH, CT 06830

510(k) NO: K012386  
PHONE NO : 203-661-0000

DEVICE: ACTICLOT PROTEIN S, MODEL 843L  
SE DECISION MADE: 14-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.  
ATTN: ELSA A LINKE  
10700 BREN ROAD WEST  
MINNETONKA, MN 55343

510(k) NO: K012342  
PHONE NO : 952-930-6309

DEVICE: AMS SOFT-TISSUE APPROXIMATION SYSTEM  
SE DECISION MADE: 05-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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APEX DENTAL MATERIALS, INC. ATTN: SCOTT LAMERAND 603 BERKLEY COURT SCHUMBERG, IL 60194	510(k) NO: K010849 PHONE NO : 847-490-1014	DEVICE: VERTEX ETCHANT SE DECISION MADE: 14-SEP-2001 510(k) STATEMENT
APPLIED BIOTECH, INC. ATTN: DAVE D SMITH 10237 FLANDERS CT. SAN DIEGO, CA 92121	510(k) NO: K012188 PHONE NO : 858-713-9614	DEVICE: SURESTEP COCAINE (COC) II DRUG SCREEN TEST SE DECISION MADE: 13-SEP-2001 510(k) STATEMENT
APPLIED SPECTRAL IMAGING, LTD. ATTN: SHOSHANA FRIEDMAN 117 AHUZAH STREET RA'ANANNA,	510(k) NO: K012103 PHONE NO : 972 9 7718130	DEVICE: BANDVIEW SYSTEM SE DECISION MADE: 14-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
AQUA WATER TREATMENT, INC. ATTN: ANIHONY WEATHERS 8195 EAST BAY BLVD. NAVARRE, FL 32566	510(k) NO: K010592 PHONE NO : 850-939-9055	DEVICE: AQUA WATER TREATMENT FOR HEMODIALYSIS SE DECISION MADE: 28-SEP-2001 510(k) STATEMENT
ARPLAY MEDICAL S.A. ATTN: RICHARD BORG 1, ROUTE DE CITEAUX IZEURE, COLE D'OR,	510(k) NO: K004023 PHONE NO : 333 802 97401	DEVICE: INTRA OPERATIVE RADIATION THERAPY SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTES MEDICAL USA, INC. ATTN: WILLIAM KIRKPATRICK 4660 LA JOLLA VILLAGE DRIVE CENTER 1, SUITE 825 SAN DIEGO, CA 92122	510(k) NO: K003988 PHONE NO : 858-550-9999	DEVICE: UROSCOPE, ARTES MEDICAL, USA SE DECISION MADE: 06-SEP-2001  510(k) SUMMARY AVAILABLE FROM FDA
ARTISCAN MEDICAL INNOVATIONS ATTN: ROBERT ANTHONY 4804 OIN OAK ROAD AKRON, OH 44333	510(k) NO: K010303 PHONE NO : 330-666-6992	DEVICE: ARTISCAN CARTILAGE STIFFNESS TESTING DEVICE SE DECISION MADE: 11-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
ASTORIA-PACIFIC, INC. 0-8000-13K ATTN: RAYMOND L PAVITT 15130 S.E. 82ND DR. P.O. BOX 830 CLAKAMAS, OR 97015-0830	510(k) NO: K010844 PHONE NO : 503-657-3010	DEVICE: ASTORIA-PACIFIC SPOTCHECK BIOTINIDASE KIT, 50 HOUR, PART NO. 8  SE DECISION MADE: 21-SEP-2001  510(k) SUMMARY AVAILABLE FROM FDA
AURORA IMAGING TECHNOLOGY, INC. ATTN: JAMES J ROGERS 39 HIGH STREET NORTH ANDOVER, MA 01845	510(k) NO: K012154 PHONE NO : 978-975-7530	DEVICE: AURORA MAGNETIC RESONANCE DIAGNOSTIC DEVICE SE DECISION MADE: 19-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA

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AUSTENAL, INC. ATTN: RONALD DUDEK 4101 WEST 51ST ST. CHICAGO, IL 60632-4287	510(k) NO: K011674 PHONE NO : 773-735-0600	DEVICE: DC - CRISTAL SE DECISION MADE: 04-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
AVITA INTERNATIONAL CORP. ATTN: ALLEN REICH 900 N. SWITZER CANYON DR. #142 FLAGSTAFF, AZ 86001	510(k) NO: K012136 PHONE NO : 520-773-9488	DEVICE: AVITA AGIL ITO1 INSTANT DIGITAL THERMOMETER SE DECISION MADE: 10-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
B. BRAUN MEDICAL, INC. ATTN: LINDA MORGAN 1601 WALLACE DR., SUITE 150 CARROLLTON, TX 75006	510(k) NO: K011975 PHONE NO : 972-245-2243	DEVICE: HORIZON OUTLOOK WITH DOSECOM SE DECISION MADE: 19-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: GEORGE M TANCOS 1884 MILES AVE. ELKHART, IN 46515-2004	510(k) NO: K012205 PHONE NO : 219-262-6928	DEVICE: GLUCOMETER DEX TEST SENSOR SE DECISION MADE: 12-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER DIAGNOSTICS CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE TARRYTOWN, NY 10591-5097	510(k) NO: K012904 PHONE NO : 914-524-2446	DEVICE: ADVIA 120 HEMATOLOGY SYSTEM, CYANIDE-FREE HIGH DETERMINATION SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
ED /KIT ATTN: PASQUALE AMATO 1 BECTON DR. MC 226 FRANKLIN LAKES, NJ 07417	510(k) NO: K012584 PHONE NO : 201-847-4513	DEVICE: MODIFICATION TO: ED DURASAFE PLUS EPIDURAL LOCK CSE NEEDLE SET SE DECISION MADE: 06-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. MUNDOSSAY SYSTEMS, MODELS 33890, 33895 ATTN: DENISE THOMPSON 1000 LAKE HAZELTINE DR. CHASKA, MN 55318-1084	510(k) NO: K012208 PHONE NO : 952-368-1202	DEVICE: ACCESS THYROGLOBULIN ANTIBODY AND CALIBRATORS ON THE ACCESS IM SE DECISION MADE: 07-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECTON DICKINSON & CO. ATTN: COLLEEN A ROHREBECK 7 LOVETON CTR. SPARKS, MD 21152-0999	510(k) NO: K012351 PHONE NO : 410-316-4988	DEVICE: BDPROBETEC ET CT/GC AMPLIFIED DNA ASSAY SE DECISION MADE: 18-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BEST MANUFACTURING COMPANY ATTN: DAVID C YOUNG 579 EDISON STREET MENLO, GA 30731	510(k) NO: K012899 PHONE NO : 706-862-2302	DEVICE: GREEN NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE SE DECISION MADE: 18-SEP-2001 510(k) STATEMENT

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BIO MEDI COM  
ATTN: COLLEEN HITTLE  
7992 CASTLEWAY DRIVE  
INDIANAPOLIS, IN 46250

510(k) NO: K012084  
PHONE NO : 317-849-1916

DEVICE: SONOREAL 3D  
SE DECISION MADE: 26-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

BIO-MEDICAL RESEARCH, LTD.  
ATTN: ROBERT DORMER  
700 13TH ST. NW  
SUITE 1200  
WASHINGTON, DC 20005

510(k) NO: K010335  
PHONE NO : 202-737-5600

DEVICE: SLENDERITONE FLEX, MODEL, 512  
SE DECISION MADE: 27-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES  
47,648  
ATTN: MARIA ZEBALLOS  
9500 JERONIMO RD.  
IRVINE, CA 92618-2017

510(k) NO: K012656  
PHONE NO : 949-598-1367

DEVICE: LIQUICHEK CARDIAC MARKERS CONTROL LT LEVEL 1,2,3, MODELS 646,6  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES  
EVEL 2, LYPHOCHEK COAGULATION LEVEL 3, MODELS 781,782,783  
ATTN: MARIA ZEBALLOS  
9500 JERONIMO RD.  
IRVINE, CA 92618-2017

510(k) NO: K012722  
PHONE NO : 949-598-1367

DEVICE: LYPHOCHEK COAGULATION CONTROL LEVEL 1, LYPHOCHEK COAGULATION I  
SE DECISION MADE: 18-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES  
ATTN: MARIA ZEBALLOS  
9500 JERONIMO RD.  
IRVINE, CA 92618-2017

510(k) NO: K012741  
PHONE NO : 949-598-1367

DEVICE: LIQUICHEK TDM CONTROL  
SE DECISION MADE: 12-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

BIOMEDICAL LIFE SYSTEMS, INC.  
ATTN: RICHARD SAXON  
P.O. BOX 1360  
VISTA, CA 92085-1360

510(k) NO: K010749  
PHONE NO : 760-727-5600

DEVICE: ELECTRO NEUROMUSCULAR STIMULATOR, MODEL "NMS-DIGITAL"  
SE DECISION MADE: 28-SEP-2001  
510(k) STATEMENT

BIOMET MANUFACTURING, INC.  
ATTN: SARA A BAILEY  
AIRPORT INDUSTRIAL PARK  
P.O. BOX 587  
WARSAW, IN 46581-0587

510(k) NO: K010657  
PHONE NO : 219-372-1568

DEVICE: COPELAND MB RESURFACING HUMERAL HEADS  
SE DECISION MADE: 14-SEP-2001

510(k) SUMMARY AVAILAABLE FROM FDA

BIOMET ORTHOPEDICS, , INC.  
ATTN: SARA A BAILEY  
P.O. BOX 587  
WARSAW, IN 46581-0587

510(k) NO: K010827  
PHONE NO : 219-267-6639

DEVICE: COPELAND MB/HA RESURFACING HUMERAL HEADS  
SE DECISION MADE: 14-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

BIONX IMPLANTS, INC.  
ATTN: TULJA ANNALA  
HERMIANKATU 6-8 L  
TAMPERE,

510(k) NO: K012334  
PHONE NO : 358 3 3165600

DEVICE: CONTOUR MENISCUS ARROW, MODELS 541110, 541113, AND 541116  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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BIOSAFE LABORATORIES, INC. TEM ATTN: JACK A MAGGIORE 100 FIELD DRIVE #240 LAKE FOREST, IL 60045	510(k) NO: K011970 PHONE NO : 773-693-0400	DEVICE: BIOSAFE CHOLESTEROL PROFILE BLOOD COLLECTION AND TRANSPORT SYS SE DECISION MADE: 26-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOTEQUE CORP. ATTN: ALLEN REICH 900 N. SWITZER CANYON DR. #142 FLAGSTAFF, AZ 86001	510(k) NO: K012526 PHONE NO : 928-773-9488	DEVICE: BIOTEQUE SCALP VEIN SET SE DECISION MADE: 14-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BISCO, INC. ATTN: KATHY LONG 1100 WEST IRVING PARK RD. SCHAUMBURG, IL 60193	510(k) NO: K012032 PHONE NO : 847-534-6106	DEVICE: FIRST SPEP SE DECISION MADE: 17-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BISCO, INC. ATTN: STEVEN J DURAY 1100 WEST IRVING PARK RD. SCHAUMBURG, IL 60193	510(k) NO: K012180 PHONE NO : 847-534-6000	DEVICE: A-WEAR SE DECISION MADE: 05-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC/MEDI-TECH ATTN: JODI L GREENIZEN ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760-1537	510(k) NO: K011664 PHONE NO : 508-652-5008	DEVICE: IMAGER II ANGIOGRAPHIC CATHETER SE DECISION MADE: 07-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB AG ATTN: STEFAN VILSMETER AMMERHALSTRASSE 8 HEIMSTETTEN,	510(k) NO: K012564 PHONE NO : 498 999 15680	DEVICE: MODIFICATION TO: VECTORVISION FRAMELESS BIOPSY SYSTEM SE DECISION MADE: 06-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB, AG ATTN: RAINER BIRKENBACH AMMERHALSTRASSE 8 HEIMSTETTEN,	510(k) NO: K010602 PHONE NO : 49 89 9918680	DEVICE: VECTORVISION HIP SE DECISION MADE: 12-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB, AG ATTN: RAINER BIRKENBACH AMMERHALSTRASSE 8 HEIMSTETTEN,	510(k) NO: K010612 PHONE NO : 49 89 9915680	DEVICE: VECTORVISION KNEE SE DECISION MADE: 06-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRANAN MEDICAL CORP. IX THC/COC/MET DRUG SCREEN DIPSTICK TEST, FASTIX OPI/MET ATTN: RAPHAEL WONG 10015 MUIRLANDS RD., SUITE E IRVINE, CA 92618	510(k) NO: K012541 PHONE NO : 949-598-7166	DEVICE: MODIFICATION TO:FASTIX THC/COC DRUG SCREEN DIPSTICK TEST, FASTI SE DECISION MADE: 04-SEP-2001 510(k) STATEMENT

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BRITESMILE, INC.  
ATTN: SHEILA HEMMON-HEYER  
49 PLAIN STREET  
NORTH ATTLEBORO, MA 02760

510(k) NO: K010935  
PHONE NO : 508-643-0434

DEVICE: BRITESMILE BARRIER MATERIAL  
SE DECISION MADE: 05-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.  
Y PER-Q-CATH DUAL LUMEN PICC CATHETER, MODEL 3246100  
ATTN: STEPHANIE A ERSKINE  
5425 WEST AMELIA EARHART DR.  
SALT LAKE CITY, UT 84116

510(k) NO: K012902  
PHONE NO : 801-595-0700

DEVICE: POLY PER-Q-CATH SINGLE LUMEN PICC CATHETER, MODEL 3143100; POI  
SE DECISION MADE: 10-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.  
ATTN: CAROL VIERLING  
13183 HARLAND DR.  
COVINGTON, GA 30014

510(k) NO: K012913  
PHONE NO : 770-385-2347

DEVICE: BARD UTAVERSE SMALL VESSEL PTA BALLOON DILATATION CATHETER  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CARD GUARD SCIENTIFIC SURVIVAL, LT510(k) NO: K012223  
ATTN: LEONID TRACHTENBERG  
2 PERERIS ST., SCIENCE PARK  
REHOVOT,

PHONE NO : 972 894 84600

DEVICE: CG-2211 SELF-CHECK ECG TRANSMITTER  
SE DECISION MADE: 10-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CARDIOFOCUS, INC.  
ATTN: JOSEPH CURTIS  
10 COMMERCE WAY  
NORION, MA 02766

510(k) NO: K011988  
PHONE NO : 508-285-1700

DEVICE: SURGICAL LIGHTSTIC 180, MODEL 180 L, MODEL 180 C  
SE DECISION MADE: 20-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CARL ZEISS JENA GMBH  
SYSTEM, OR FF450 PLUS VISUPAC SYSTEM  
ATTN: JOHANNATHAN S KAHAN  
555 THIRTEENTH STREET, N.W.  
WASHINGTON, DC 20004-1109

510(k) NO: K011877  
PHONE NO : 202-637-5794

DEVICE: FF450 PLUS FUNDUS CAMERA AND VISUPAC DIGITAL IMAGE ARCHIVING S  
SE DECISION MADE: 26-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CATHEFFECTS, LLC.  
CABLE  
ATTN: SHAWN FOJTIK  
1100 MELODY LANE; SUITE 108  
ROSEVILLE, CA 95678

510(k) NO: K011361  
PHONE NO : 916-677-1790

DEVICE: DESAI VECTORCATH MAPPING CATHETER, DESAI VECTORCATH CONNECTOR  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CERIUM OPTICAL TECHNOLOGIES, INC.  
ATTN: SOL AISENBERG  
36 BRADFORD ROAD  
NATICK, MA 01760

510(k) NO: K012298  
PHONE NO : 508-651-0140

DEVICE: THE INTUITIVE COLORIMETER  
SE DECISION MADE: 26-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CHROMATICS COLOR SCIENCES INTL., I510(k) NO: K001687  
ATTN: THOMAS M TSAKERIS  
16809 BRIARDALE ROAD  
ROCKVILLE, MD 20855

PHONE NO : 301-330-2076

DEVICE: COLORMATE TLC BILITEST SYSTEM  
SE DECISION MADE: 13-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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CHURCHILL MEDICAL SYSTEMS, INC. ATTN: KEITH PALUCH 87 VENTURE DR. DOVER, NH 03820	510(k) NO: K011888 PHONE NO : 603-743-5988	DEVICE: PRESSURE ACTIVATED CHECK VALVE SE DECISION MADE: 10-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
CHURCHILL MEDICAL SYSTEMS, INC. ATTN: KEITH PALUCH 87 VENTURE DR. DOVER, NH 03820	510(k) NO: K012157 PHONE NO : 603-743-5988	DEVICE: CHURCHILL MEDICAL SYSTEMS STOPCOCK SE DECISION MADE: 11-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
CIRCON VIDEO ATTN: JERRY CROUTHERS 6500 HOLLISTER AVE. SANTA BARBARA, CA 93117	510(k) NO: K011848 PHONE NO : 805-685-5100	DEVICE: CIRCON AEH-4 ELECTROHYDRAULIC LITHOTRIPSY PROBE SE DECISION MADE: 11-SEP-2001 510(k) STATEMENT
CIRCON VIDEO ATTN: WAYNE B STIGNER 6500 HOLLISTER AVE. SANTA BARBARA, CA 93117	510(k) NO: K012153 PHONE NO : 805-685-5100	DEVICE: LOWSLEY SUPRAPUBIC TRACTOR SE DECISION MADE: 19-SEP-2001 510(k) STATEMENT
CLINICAL CONTROLS, INC. ATTN: JAMES F GODFREY 12038 CENTRALIA ROAD, SUITE C HAWAIIAN GARDENS, CA 90716	510(k) NO: K012907 PHONE NO : 562-809-3389	DEVICE: LIQUISPX LIQUID SALIVA OR UNRINE DRUG OF ABUSE CONTROL SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
COBE CARDIOVASCULAR, INC. ATTN: LYNNE LEONARD 14401 WEST 65TH WAY ARVADA, CO 80004	510(k) NO: K012898 PHONE NO : 303-467-6586	DEVICE: MODIFICATION TO: CSC14 BLOOD CARDIOPLEGIA SYSTEM SE DECISION MADE: 17-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
COLLAGEN MATRIX, INC. ATTN: SHU-TUNG LI 509 COMMERCE STREET FRANKLIN LAKES,, NJ 07417	510(k) NO: K012814 PHONE NO : 201-405-1477	DEVICE: COLLAGEN NERVE CUFF SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: LISA HOPKINS 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K010450 PHONE NO : 800-346-2686	DEVICE: LIVER TAMPONADE BALLOON SE DECISION MADE: 06-SEP-2001  510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. 035" DELIVERY SYSTEM ATTN: CHARLES (CHUCK) J RYAN 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K012590 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT ON OPTA PRO . SE DECISION MADE: 07-SEP-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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CORGENIX, INC.  
ATTN: Nanci Dexter  
12061 TEJON ST.  
WESTMINSTER, CO 80234

510(k) NO: K013018  
PHONE NO : 303-457-4345

DEVICE: REAADS ANTI-PHOSPHATIDYLSERINE IGA SEMI-QUANTITATIVE TEST KIT  
SE DECISION MADE: 20-SEP-2001  
510(k) STATEMENT

CORGENIX, INC.  
ATTN: Nanci Dexter  
12061 TEJON ST.  
WESTMINSTER, CO 80234

510(k) NO: K013077  
PHONE NO : 303-457-4345

DEVICE: REAADS ANTI-BETA 2 GLYCOPROTEIN I IGM TEST KIT  
SE DECISION MADE: 28-SEP-2001  
510(k) STATEMENT

CORGENIX, INC.  
ATTN: Nanci Dexter  
12061 TEJON ST.  
WESTMINSTER, CO 80234

510(k) NO: K013079  
PHONE NO : 303-457-4345

DEVICE: REAADS ANTI-BETA 2 GLYCOPROTEIN I IGA TEST KIT  
SE DECISION MADE: 28-SEP-2001  
510(k) STATEMENT

CORGENIX, INC.  
ATTN: Nanci Dexter  
12061 TEJON ST.  
WESTMINSTER, CO 80234

510(k) NO: K013080  
PHONE NO : 303-457-4345

DEVICE: REAADS ANTI-BETA 2 GLYCOPROTEIN I IGG TEST KIT  
SE DECISION MADE: 28-SEP-2001  
510(k) STATEMENT

CP MEDICAL  
ATTN: MARY ANN GREENAWALT  
836 N.E. 24TH AVE.  
PORTLAND, OR 97232

510(k) NO: K010621  
PHONE NO : 503-232-1555

DEVICE: ACCU-SPACE ABSORBABLE SEEDING SPACERS  
SE DECISION MADE: 04-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

CYNOSURE, INC.  
ATTN: GEORGE CHO  
10 ELIZABETH DR.  
CHELMSFORD, MA 01824

510(k) NO: K011828  
PHONE NO : 978-256-4200

DEVICE: CYNOSURE ACCLAIM DERMATOLOGY LASER  
SE DECISION MADE: 07-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.  
ATTN: ELAINE H KINDELL  
P.O. BOX 6101  
GLASGOW BLDG. 500  
NEWARK, DE 19714-6101

510(k) NO: K012233  
PHONE NO : 302-631-6564

DEVICE: STRATUS CS TROPONIN I CALIBRATOR  
SE DECISION MADE: 11-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012468  
PHONE NO : 302-631-6276

DEVICE: MODIFICATION TO N/T PROTEIN CONTROL SL  
SE DECISION MADE: 04-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012470  
PHONE NO : 302-631-6276

DEVICE: MODIFICATION TO N PROTEIN STANDARD SL  
SE DECISION MADE: 28-SEP-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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DATEX-OMEDA IES ATTN: JOEL C KENT 86 PILGRIM ROAD NEEDHAM, MA 02492	510(k) NO: K012837  PHONE NO : 781-449-8685	DEVICE: MODIFICATION TO: DATEX-OMEDA CARDIOCAP 5 (REV B) AND ACCESSOR  SE DECISION MADE: 14-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
DEBIOTECH S.A. ATTN: SEAN CURRY 16787 BERNARDO CENTER DRIVE SUITE A-1 SAN DIEGO, CA 92128-2504	510(k) NO: K011868  PHONE NO : 858-675-8200	DEVICE: ENTERAL EXPRES PUMP UNIT, ENTERAL EXPRES GIVING SETS SE DECISION MADE: 04-SEP-2001  510(k) SUMMARY AVAILABLE FROM FDA
DEPUY, INC. LPS TIBIAL BEARING ATTN: JANET G JOHNSON 700 ORTHOPAEDIC DR. P.O. BOX 988 WARSAW, IN 46581-0988	510(k) NO: K011810  PHONE NO : 219-371-4907	DEVICE: ORTHOGENESIS LPS PROXIMAL TIBIAL REPLACEMENT AND ORTHOGENESIS SE DECISION MADE: 07-SEP-2001  510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTIC PRODUCTS CORP. OO TESTS ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K012301  PHONE NO : 310-645-8200	DEVICE: IMMULITE 2000 DIGOXIN, MODELS L2KDI2 (200 TESTS) AND L2KDI6 (6 SE DECISION MADE: 19-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
DIAMEDIX CORP. ATTN: LYNNE STIRLING 2140 NORTH MIAMI AVE. MIAMI, FL 33127	510(k) NO: K012795  PHONE NO : 305-324-2354	DEVICE: DIAMEDIX IS-ANTI-GLIADIN IGG TEST SYSTEM SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILAABLE FROM FDA
DIAMEDIX CORP. ATTN: LYNNE STIRLING 2140 NORTH MIAMI AVE. MIAMI, FL 33127	510(k) NO: K012797  PHONE NO : 305-324-2354	DEVICE: DIAMEDIX IS-ANTI-GLIADIN IGA TEST SYSTEM SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
DIAMODENT ATTN: JEFF RASSOLI 2737 EAST REGAL PARK AVENUE ANAHEIM, CA 92806	510(k) NO: K010619  PHONE NO : 714-632-3206	DEVICE: UCLA AND UNIVERSAL ABUTMENTS SE DECISION MADE: 28-SEP-2001 510(k) STATEMENT
DIDECO OFT VENOUS RESERVOIR BAG, WITH BIOCOMPATABLE TREATMENT SUR ATTN: LYNNE LEONARD 14401 W. 65TH WAY ARVADA, CO 80004-3599	510(k) NO: K010478  PHONE NO : 303-467-6586	DEVICE: DIDECO D901 LILLIPUT HOLLOW FIBER OXYGENATOR WITH OR WITHOUT S SE DECISION MADE: 27-SEP-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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DIGENE CORP.  
ATTN: MARK A DEL VECCHIO  
1201 CLOPPER RD  
GAITHERSBURG, MD 20878

510(k) NO: K010891  
PHONE NO : 301-944-7092

DEVICE: MODIFICATION TO HYBRID CAPTURE II CT/GC TEST, MODEL 03M90-01  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

DIGENE CORP.  
ATTN: MARK A DEL VECCHIO  
1201 CLOPPER RD  
GAITHERSBURG, MD 20878

510(k) NO: K010892  
PHONE NO : 301-944-7092

DEVICE: MODIFICATION HYBRID CAPTURE II CT-ID DNA TEST, MODEL 03M91-01  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

DIGENE CORP.  
1  
ATTN: MARK A DEL VECCHIO  
1201 CLOPPER RD  
GAITHERSBURG, MD 20878

510(k) NO: K010893  
PHONE NO : 301-944-7092

DEVICE: MODIFICATION TO HYBRID CAPTURE 2 GC-ID DNA TEST, MODEL 03M92-0  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

DR. ALBERT ZICKMANN  
ATTN: ALBERT ZICKMANN  
5455 N. SHERIDAN ROAD  
#3608  
CHICAGO, IL 60640

510(k) NO: K010882  
PHONE NO : 773-769-2622

DEVICE: BLUE SKY BIO DENTAL IMPLANT SYSTEM  
SE DECISION MADE: 28-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

DRAGER MEDIZINTECHNIK GMBH  
ATTN: JAMES J BRENNAN  
3135 QUARRY ROAD  
TELFORD, PA 18969

510(k) NO: K012177  
PHONE NO : 215-721-5400

DEVICE: VENIVIEW, MODEL 8414095  
SE DECISION MADE: 04-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

DREW SCIENTIFIC LTD.  
ATTN: ANDREW KENNEY  
PARK RD., TELEMETER BLDG.  
BARROW IN FURNESS,

510(k) NO: K012152  
PHONE NO : 441 229 432089

DEVICE: DS30 HCY BLOOD COLLECTION TUBES  
SE DECISION MADE: 18-SEP-2001  
510(k) STATEMENT

E-MED INNOVATIONS, INC.  
ATTN: HUGH E HACKNEY  
2200 ROSS AVENUE, SUITE 2200  
DALLAS, TX 75201-6776

510(k) NO: K011898  
PHONE NO : 214-740-8000

DEVICE: E-STETH ELECTRONIC STETHOSCOPE  
SE DECISION MADE: 14-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ELECTRICAL GEODESICS, INC.  
ATTN: ROBERT S MOQUATE  
3636 E. COLUMBINE DRIVE  
PHOENIX, AZ 85032-7372

510(k) NO: K012079  
PHONE NO : 602-788-5651

DEVICE: GEODESIC EEG SYSTEM, MODEL 200  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ENDOCARDIAL SOLUTIONS, INC.  
ATTN: ERIC W KOEHLER  
1350 ENERGY LN., SUITE 110  
ST. PAUL, MN 55108

510(k) NO: K012926  
PHONE NO : 651-523-6934

DEVICE: MODIFICATION TO ENSITE 3000 SYSTEM, MODEL EE3000  
SE DECISION MADE: 28-SEP-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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ETYMONIC DESIGN, INC.  
ATTN: WILLIAM A COLE  
41 BYRON AVE.  
DORCHESTER, ONTARIO,

510(k) NO: K012306  
PHONE NO : 519 268 3313

DEVICE: AUDIOSCAN VERIFIT, MODEL VF-1  
SE DECISION MADE: 21-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

EUROLINK LLC.  
ATTN: WILLIAM RITIMAN  
77 LOCKSLEY RD.  
LYNNFIELD, MA 01940

510(k) NO: K011387  
PHONE NO : 781-334-6654

DEVICE: NEUROTHERM, MODEL JK4  
SE DECISION MADE: 06-SEP-2001  
510(k) STATEMENT

EXELINT INTL. CO.  
ATTN: ARMAND HAMID  
5840 WEST CERVINELA AVE.  
LOS ANGELES, CA 90045

510(k) NO: K011405  
PHONE NO : 310-649-0707

DEVICE: EXEL INJECTION PLUG WITH CAP  
SE DECISION MADE: 27-SEP-2001  
510(k) STATEMENT

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

510(k) NO: K011964  
PHONE NO : 781-229-1500

DEVICE: INSIGHT MILLENNIUM PLUS  
SE DECISION MADE: 20-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

FISHER DIAGNOSTICS  
ATTN: NADIA GREENIDGE  
8365 VALLEY PIKE  
MIDDLETOWN, VA 22645-0307

510(k) NO: K010750  
PHONE NO : 540-869-3200

DEVICE: PACIFIC HEMOSTASIS INR CONTROL PLASMAS, MODEL CATALOG 100560  
SE DECISION MADE: 07-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012062  
PHONE NO : 858-587-1147

DEVICE: PF2  
SE DECISION MADE: 27-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012078  
PHONE NO : 858-587-1147

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

GE MEDICAL SYSTEMS  
ATTN: GEOFFREY COCHRANE  
8380 DARROW ROAD  
TWINSBURG, OH 44087

510(k) NO: K012775  
PHONE NO : 330-487-6638

DEVICE: GE POSITRACE/DISCOVERY VI PET/CT DUAL MODE ONCOLOGY SCANNER  
SE DECISION MADE: 18-SEP-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: K012836  
PHONE NO : 262-544-3894

DEVICE: MODIFICATION TO: LIGHTSPEED PLUS MOBILE CT SYSTEM  
SE DECISION MADE: 07-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012970  
PHONE NO : 262-544-3894

DEVICE: GE SIGNA ASSET IMAGING OPTION  
SE DECISION MADE: 24-SEP-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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GENERAL ELECTRIC CO.  
ATTN: KEVIN M MURROCK  
8380 DARROW ROAD  
TWINSBURG, OH 44087

510(k) NO: K012568  
PHONE NO : 330-487-6635

DEVICE: GE VISION NUCLEAR MEDICINE WORKSTATION  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

GETINGE/CASTLE, INC.  
C, 522HC, AND 533HC  
ATTN: FREDERICK R CAIT  
1777 EAST HENRIETTA RD.  
ROCHESTER, NY 14623-3133

510(k) NO: K012573  
PHONE NO : 716-272-5013

DEVICE: CASTLE 400HC/500HC SERIES STEAM STERILIZER, MODELS 422HC, 433H  
SE DECISION MADE: 05-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

GI SUPPLY  
ATTN: FRANK CARTER  
200 GRANDVIEW AVE.  
CAMP HILL, PA 17011

510(k) NO: K012411  
PHONE NO : 717-761-1171

DEVICE: HP-ONE  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

GREINER VACUETTE NORTH AMERICA, IN  
ATTN: JUDI SMITH  
P.O. BOX 103  
BALDWIN, MD 21013

510(k) NO: K012043  
PHONE NO : 410-592-2060

DEVICE: VACUETTE EDTA K2 GEL TUBES  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

GUIDANT CORP.  
ATTN: SARA MOJARRAD  
3200 LAKESIDE DR.  
P.O. BOX 58167  
SANTA CLARA, CA 95054-2807

510(k) NO: K012050  
PHONE NO : 408-845-1067

DEVICE: VIATRAC 14 PLUS PERIPHERAL DILATATION CATHETER  
SE DECISION MADE: 06-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

HARRISON CBP SEMINARS  
ATTN: SANG HARRISON  
P.O. BOX 1590  
EVANSTON, WY 82931-1590

510(k) NO: K010851  
PHONE NO : 307-789-2088

DEVICE: HARRISON HAND HELD ADJUSTING INSTRUMENT  
SE DECISION MADE: 18-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

HELENA LABORATORIES  
ATTN: PATRICIA FRANKS  
1530 LINDBERGH DR.  
P.O. BOX 752  
BEAUMONT, TX 77704

510(k) NO: K012723  
PHONE NO : 409-842-3714

DEVICE: PLATELETWORKS  
SE DECISION MADE: 28-SEP-2001

510(k) STATEMENT

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

510(k) NO: K012250  
PHONE NO : 443-367-5518

DEVICE: RAICHEM MULTI-ANALYTE CALIBRATOR  
SE DECISION MADE: 24-SEP-2001  
510(k) STATEMENT

HMB MEDICAL CONCEPTS, LTD.  
ATTN: GAVIN MCLACHLAN  
1695 RIDGE HAVEN RUN  
ALPHARETTA, GA 30022

510(k) NO: K011979  
PHONE NO : 678-624-9718

DEVICE: ALLERSHARP ALLERGY SKIN TESTER  
SE DECISION MADE: 14-SEP-2001  
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
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HOWMEDICA OSTEONICS CORP. ATTN: KAREN ARLEMA 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K012870 PHONE NO : 201-760-8187	DEVICE: XIA STAINLESS STEEL SYSTEM SE DECISION MADE: 24-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
HUNTLEIGH HEALTHCARE, INC. ATTN: AUDREY WITKO 40 CHRISTOPHER WAY EATONTOWN, NJ 07724-3327	510(k) NO: K012008 PHONE NO : 732-578-9898	DEVICE: STS RANGE , MODELS STS20, STS30, STS40 SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
HYPOGUARD USA, INC. EEN REAGENT STRIP FOR URINALYSIS, ATTN: BRUCE MACFARLANE 5182 WEST 76TH ST. MINNEAPOLIS, MN 55439	510(k) NO: K010973 CAT. # D11000 PHONE NO : 952-646-3188	DEVICE: DIASCREEN 50 URINE CHEMISTRY ANALYZER, MODEL # 1242-00; DIASCR SE DECISION MADE: 11-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
IMPLANT INNOVATIONS, INC. ATTN: MARY L VERSTYNEN 56 E BELL DRIVE WARSAW, IN 46582	510(k) NO: K012047 PHONE NO : 219-267-6639	DEVICE: 3I CALCIUM SULFATE BONE CEMENT SE DECISION MADE: 19-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
IMPLANT INNOVATIONS, INC. ATTN: JACQUELYN A HUGHES 4555 RIVERSIDE DR. PALM BEACH GARDENS, FL 33410	510(k) NO: K012911 PHONE NO : 561-776-6819	DEVICE: 3I LOCATER ABUIMENT SYSTEM SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
IMPLEX CORP. ATTN: ROBERT A POGGIE 80 COMMERCE DR. ALLENDALE, NJ 07401-1600	510(k) NO: K012866 PHONE NO : 201-818-1800	DEVICE: THE NEXGEN TMT TIBIA, MODELS 00-5886-XXYY, 05-120-XXYY-0 SE DECISION MADE: 26-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
INSTRUMENTATION LABORATORY CO. ATTN: CAROL MARELE 113 HARTWELL AVE. LEXINGTON, MA 02421	510(k) NO: K012768 PHONE NO : 781-861-4467	DEVICE: HEMOSIL RECOMBI PLASTIN SE DECISION MADE: 18-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
INSTRUMENTATION LABORATORY CO. ATTN: CAROL MARELE 113 HARTWELL AVE. LEXINGTON, MA 02421	510(k) NO: K012901 PHONE NO : 781-861-4467	DEVICE: COLOR-MONOGEN SE DECISION MADE: 27-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
INTERPORE CROSS INIL. , 6173, 6174, 6175, 6176, 6177 ATTN: LYNN M RODARTI 181 TECHNOLOGY DR. IRVINE, CA 92618-2402	510(k) NO: K012871 PHONE NO : 949-543-3200	DEVICE: SYNERGY TI INTEGRAL OPEN SCREWS MODELS # 6193, 6194, 6195, 6196 SE DECISION MADE: 13-SEP-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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INVACARE CORP.  
ATTN: RAE ANN FARROW  
ONE INVACARE WAY  
P.O. BOX 4028  
ELYRIA, OH 44036-2125

510(k) NO: K012927  
PHONE NO : 440-329-6356

DEVICE: M71 POWER WHEELCHAIR  
SE DECISION MADE: 19-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012332  
PHONE NO : 305-418-2320

DEVICE: JAS CARBON DIOXIDE LIQUID REAGENT  
SE DECISION MADE: 06-SEP-2001  
510(k) STATEMENT

JMS CO., LTD.  
ATTN: KEISUKE URATOMI  
12-17, KAKO-MACHI, NAKA-KU  
HIROSHIMA,

510(k) NO: K002352  
PHONE NO : 818 224 35806

DEVICE: JMS A.V. FISTULA NEEDLE SET ACCORDION TYPE  
SE DECISION MADE: 06-SEP-2001  
510(k) STATEMENT

JMS CO., LTD.  
ATTN: KEISUKE URATOMI  
12-17, KAKO-MACHI, NAKA-KU  
HIROSHIMA 730-8652,

510(k) NO: K002394  
PHONE NO : 818 224 35806

DEVICE: JMS APHERESIS NEEDLE SET ACCORDION TYPE  
SE DECISION MADE: 05-SEP-2001  
510(k) STATEMENT

JOHNSON & JOHNSON MEDICAL (CHINA)  
ATTN: BEN TANG  
#75 NAN GU ZHI ROAD  
MONHANG, SHANGHAI,

510(k) NO: K012124  
PHONE NO : 862 146 435010

DEVICE: MERSILK BLACK SILK BRAIDED NON-ABSORBABLE SUTURE, USP  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

KARL STORZ ENDOSCOPY  
ATTN: JAMES A LEE  
600 CORPORATE POINTE  
CULVER CITY, CA 90230-7600

510(k) NO: K011841  
PHONE NO : 310-410-2769

DEVICE: KSEA SAWAHLE ELECTROMECHANICAL MORCELLATOR  
SE DECISION MADE: 10-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

KENSEY NASH CORP.  
ATTN: JULIE N BRODERICK  
55 EAST UWCHLAN AVE.  
MARSH CREEK CORP. CENTER  
EXTON, PA 19341-1247

510(k) NO: K011943  
PHONE NO : 610-594-7113

DEVICE: IMPRO VISE ABSORBABLE CEMENT FLOW RESTRICTOR  
SE DECISION MADE: 19-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KERR DENTAL MATERIALS CENTER  
ATTN: COLLEEN BOSWELL  
1717 WEST COLLINS AVE.  
ORANGE, CA 92867

510(k) NO: K011908  
PHONE NO : 714-516-7484

DEVICE: OPTIBOND SOLO PLUS 3  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. MELLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012432  
PHONE NO : 212-986-2230

DEVICE: MODIFICATION TO CLEARFIL PHOTO BOND  
SE DECISION MADE: 04-SEP-2001

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-SEP-2001 THROUGH 30-SEP-2001

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KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012436  
PHONE NO : 212-986-2230

DEVICE: MODIFICATION TO ALLOY PRIMER  
SE DECISION MADE: 04-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012438  
PHONE NO : 212-986-2230

DEVICE: MODIFICATION TO PANAVIA 21  
SE DECISION MADE: 05-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012440  
PHONE NO : 212-986-2230

DEVICE: MODIFICATION TO CLEARFIL LINER BOND 2V  
SE DECISION MADE: 05-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012441  
PHONE NO : 212-986-2230

DEVICE: PANAVIA F  
SE DECISION MADE: 06-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012442  
PHONE NO : 212-986-2230

DEVICE: MODIFICATION TO CLEARFIL SE BOND  
SE DECISION MADE: 10-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012703  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL CORE NEW BOND  
SE DECISION MADE: 10-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012704  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL ST OPAQUER  
SE DECISION MADE: 10-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012705  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL PHOTO CORE  
SE DECISION MADE: 11-SEP-2001

510(k) STATEMENT



SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
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KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012707  
PHONE NO : 212-986-2230

DEVICE: ESTENIA  
SE DECISION MADE: 13-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012729  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL REPAIR  
SE DECISION MADE: 13-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012730  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL PORCELAIN BOND ACTIVATOR  
SE DECISION MADE: 13-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012733  
PHONE NO : 212-986-2230

DEVICE: CARIES DETECTOR  
SE DECISION MADE: 14-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012734  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL NEW BOND  
SE DECISION MADE: 14-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012735  
PHONE NO : 800-879-1676

DEVICE: CLEARFIL DC CEMENT  
SE DECISION MADE: 14-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012737  
PHONE NO : 212-986-2230

DEVICE: CHROMA ZONE COLOR STAIN  
SE DECISION MADE: 14-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

KURARAY MEDICAL INC.  
ATTN: MASAYA SASAKI  
30TH FL. METLIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

510(k) NO: K012740  
PHONE NO : 212-986-2230

DEVICE: CLEARFIL AP-X  
SE DECISION MADE: 14-SEP-2001

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-SEP-2001 THROUGH 30-SEP-2001

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KURARAY MEDICAL INC. ATTN: MASAYA SASAKI 30TH FL. METLIFE BUILDING 200 PARK AVENUE NEW YORK, NY 10166	510(k) NO: K012742 PHONE NO : 212-986-2230	DEVICE: TEETHMATE F-1 SE DECISION MADE: 14-SEP-2001  510(k) SUMMARY AVAILABLE FROM FDA
LEAD-LOK, INC. ATTN: CHRIS HEALY 500 AIRPORT WAY SANDPOINT, ID 83864	510(k) NO: K010431 PHONE NO : 208-263-5071	DEVICE: LEAD-LOK REUSABLE TENS/ NMES ELECTRODES SE DECISION MADE: 06-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
LH MEDICAL PRODUCTS, INC. ATTN: LONNIE HUTSON 301 EAST ARROW HWY., SUITE 104 SAN DIMAS, CA 91773	510(k) NO: K011340 PHONE NO : 877-592-0523	DEVICE: LH 450 ENTERAL FEEDING BAG PUMP SET W/INTEGRATED Y-PORT SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
LH MEDICAL PRODUCTS, INC. ATTN: LONNIE HUTSON 301 EAST ARROW HWY., SUITE 104 SAN DIMAS, CA 91773	510(k) NO: K011341 PHONE NO : 877-592-0523	DEVICE: LH400 YES-SET Y-PORT ENTERAL SPIKE PUMP SET SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
LH MEDICAL PRODUCTS, INC. ATTN: LONNIE HUTSON 301 EAST ARROW HWY., SUITE 104 SAN DIMAS, CA 91773	510(k) NO: K011343 PHONE NO : 877-592-0523	DEVICE: LH 500 ENTERAL FEEDING GRAVITY BAG SET SE DECISION MADE: 21-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
M.I.S. IMPLANTS TECHNOLOGIES LTD. ATTN: AHAVA STEIN BEIT HAPA'AMON, SUITE 206 BOX 124;20 HATA'AS ST. KFAR SABA,	510(k) NO: K003191 PHONE NO : 729-767-0002	DEVICE: MIS IMPLANT SYSTEM DECIIVE SE DECISION MADE: 28-SEP-2001  510(k) STATEMENT
MACROPORE, INC. ATTN: KENNETH K KLEINHENZ 6740 TOP GUN ST. SAN DIEGO, CA 92121	510(k) NO: K012413 PHONE NO : 858-458-0900	DEVICE: MACROPORE FX, PS, NS, LP SE DECISION MADE: 18-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MANUFACTURERA DENIAL CONTINENTAL ATTN: GARY S MOCNIK 27881 LA PAZ ROAD, #G 316 LAGUNA NIGUEL, CA 92677	510(k) NO: K011785 PHONE NO : 949-363-2953	DEVICE: NOVEL PRINT CYAN ALGINATES SE DECISION MADE: 04-SEP-2001 510(k) STATEMENT
MARCONI MEDICAL SYSTEMS, INC. ATTN: ROBERT L TUROCY 595 MINER ROAD HIGHLAND HEIGHTS, OH 44143	510(k) NO: K012009 PHONE NO : 440-483-3528	DEVICE: MX8000 IDT CT SYSTEM SE DECISION MADE: 13-SEP-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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MATANG MFG. SDN. BHD. D PROTEIN CONTENT LABELING CLAIM OF 50 MICROGRAMS OR LESS ATTN: KOK-KEE HON 6324 MEETING HOUSE WAY ALEXANDRIA, VA 22312-1718	510(k) NO: K012558 PHONE NO : 703-941-7656	DEVICE: POWDER FREE LATEX PATIENT EXAMINATION GLOVES WITH ALOE VERA AN  SE DECISION MADE: 17-SEP-2001 510(k) STATEMENT
MEDICAL DEVICE TECHNOLOGIES, INC. ATTN: KARL SWARTZ 3600 S.W. 47TH AVE. GAINESVILLE, FL 32608	510(k) NO: K011790 PHONE NO : 352-338-0440	DEVICE: MICROCRUISER PLUS INTRODUCER SET SE DECISION MADE: 05-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL ELECTRONIC SYSTEMS, LLC ATTN: ERIKA B AMMIRATI 6363 GREENWICH DRIVE SUITE 220 SAN DIEGO, CA 92122	510(k) NO: K012352 PHONE NO : 650-949-2768	DEVICE: SQA, SPERM QUALITY ANALYZER SE DECISION MADE: 21-SEP-2001  510(k) STATEMENT
MEDICAL RESEARCH LABORATORIES, INC ATTN: JOEL ORLINSKY 1000 ASBURY DR. NO.17 BUFFALO GROVE, IL 60089	510(k) NO: K012030 PHONE NO : 847-520-0300	DEVICE: PORTABLE INTENSIVE CARE UNIT SE DECISION MADE: 24-SEP-2001 510(k) STATEMENT
MEDISON AMERICA, INC. ATTN: GARY J ALLSEBROOK 16303 PANORAMIC WAY SAN LEANDRO, CA 94578-1116	510(k) NO: K012867 PHONE NO : 510-276-2648	DEVICE: SONOACE 9900 DIAGNOSTIC ULTRASOUND SYSTEM SE DECISION MADE: 12-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDISON AMERICA, INC. ATTN: GARY J ALLSEBROOK 16303 PANORAMIC WAY SAN LEANDRO, CA 94578-1116	510(k) NO: K012887 PHONE NO : 510-276-2648	DEVICE: SA6000II DIAGNOSTIC ULTRASOUND SYSTEM SE DECISION MADE: 12-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDLINE INDUSTRIES, INC. ATTN: STACEY L BOLEN ONE MEDLINE PLACE MUNDELEIN, IL 60060-4486	510(k) NO: K011240 PHONE NO : 847-837-2843	DEVICE: EVENCARE BLOOD GLUCOSE MONITORING SYSTEM SE DECISION MADE: 13-SEP-2001 510(k) STATEMENT
MEDOC LTD. ADVANCED MEDICAL SYSTEMS ATTN: ANN QUINLAN-SMITH 11660 WAYZATA BLVD. MINNETONKA, MN 55305	510(k) NO: K010981 PHONE NO : 952-593-1553	DEVICE: GSA GENITO SENSORY ANALYZER SE DECISION MADE: 20-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC PERFUSION SYSTEMS MC 50T ATTN: MARIE HOLM 7611 NORTHLAND DR. MINNEAPOLIS, MN 55428	510(k) NO: K012743 PHONE NO : 763-391-9183	DEVICE: TRILLIUM TRI-OPTIC MEASUREMENT CELL, MODEL TMC 25T, TMC38 T, T  SE DECISION MADE: 14-SEP-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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MEDTRONIC PERFUSION SYSTEMS ) ATTN: MARIE HOLM 7611 NORTHLAND DR. MINNEAPOLIS, MN 55428	510(k) NO: K012747 PHONE NO : 763-391-9183	DEVICE: TRILLIUM BIO DISPOSABLE BLOOD FLOW PROBE (MODELS DP38T & FP38P) SE DECISION MADE: 14-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC PERFUSION SYSTEMS FACE, MODEL 351T ATTN: MARIE HOLM 7611 NORTHLAND DR. MINNEAPOLIS, MN 55428	510(k) NO: K013084 PHONE NO : 763-391-9183	DEVICE: AFFINITY 38 MICON ARTERIAL FILTER WITH TRILLIUM BIOPASSIVE SUR SE DECISION MADE: 27-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC PHYSIO-CONTROL CORP. ATTN: SHERRI L POCOCK 11811 WILLOWS RD NE P.O. BOX 97006 REDMOND, WA 98073-9706	510(k) NO: K012428 PHONE NO : 425-867-4332	DEVICE: MODIFICATION TO: LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC SOFAMOR DANEK, INC. ATTN: RICHARD W TREHARNE 1800 PYRAMID PL. MEMPHIS, TN 38132	510(k) NO: K003780 PHONE NO : 901-396-3133	DEVICE: VERTEX RECONSTRUCTION SYSTEM SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MERITS HEALTH PRODUCTS., INC. ATTN: WINSTON ANDERSON P.O. BOX 150356 CAPE CORAL, FL 33915	510(k) NO: K012802 PHONE NO : 941-772-0579	DEVICE: MP3CF ELECTRIC WHEELCHAIR SE DECISION MADE: 18-SEP-2001 510(k) STATEMENT
MICRO HEALTH SYSTEMS INC. ATTN: ROBERT BARNES 7407 DOVER LANE PARKLAND, FL 33067	510(k) NO: K011981 PHONE NO : 954-575-1076	DEVICE: MHS 5000 SE DECISION MADE: 05-SEP-2001 510(k) STATEMENT
MICROMEDICAL INDUSTRIES, LTD. ATTN: STEPHEN CRESSWELL 11 TECHNOLOGY DR. LABRADOR, QUEENSLAND,	510(k) NO: K012540 PHONE NO : 011 61 755739742	DEVICE: BLY-501 ADAPTOR SE DECISION MADE: 26-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MOLDED PRODUCTS ATTN: ELISE JOHNSTON 601 DURANT ST. HARLAN, IA 51537	510(k) NO: K010712 PHONE NO : 712-755-5557	DEVICE: DIALYSATE LINE WITH CONNECTORS/RE-USE WASH-OUT LINES SE DECISION MADE: 27-SEP-2001 510(k) STATEMENT
MONAGHAN MEDICAL CORP. ATTN: JAMES A COCHIE 5 LATOUR AVE., SUITE 1600 P.O. BOX 2805 PLATTSBURGH, NY 12901	510(k) NO: K012939 PHONE NO : 518-561-7330	DEVICE: AEROVENT II CHC COLLAPSIBLE HOLDING CHAMBER SE DECISION MADE: 28-SEP-2001 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
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MRC SYSTEMS GMEH ATTN: JORG STEIN HANS-BUNTE-STR. 10 HEIDELBERG,	510(k) NO: K011816 PHONE NO : 496 221 1380300	DEVICE: MINI MULTILEAF COLLIMATOR, MODEL KMI SE DECISION MADE: 07-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
MRI DEVICES CORP. ATTN: TOM SCHUBERT 1515 PARAMOUNT DR. SUITE A WAUKESHA, WI 53186	510(k) NO: K013099 PHONE NO : 262-524-1402	DEVICE: MODIFICATION TO: QWH-420 WRIST ARRAY COIL SE DECISION MADE: 25-SEP-2001 510(k) STATEMENT
NAKANISHI, INC. ATTN: HIROJI SEKIGUCHI 340 KAMIHINATA, KANUMA-SHI TOCHIGI-KEN,	510(k) NO: K011926 PHONE NO : 028 964 3380	DEVICE: ELEC-MATE E SE DECISION MADE: 11-SEP-2001 510(k) STATEMENT
NATIONAL CUSTOM ENT., INC. 05,6500,6700,6006C & 20009, MODEL ATTN: DON PELLETIER 1133 EAST CLIFF RD. BURNSVILLE, MN 55337	510(k) NO: K012229 PHONE NO : 952-890-1360	DEVICE: SCALE-TRONIX 48, 2001, 2009,2700,3003,4004, 4800, 5005,5700,60 SE DECISION MADE: 10-SEP-2001 510(k) STATEMENT
NATIONAL CUSTOM ENT., INC. ATTN: DON PELLETIER 1133 EAST CLIFF RD. BURNSVILLE, MN 55337	510(k) NO: K012259 PHONE NO : 952-890-1360	DEVICE: MEDFUSION 2001 & 2010, MODEL N7215IWC SE DECISION MADE: 12-SEP-2001 510(k) STATEMENT
NATIONAL CUSTOM ENT., INC. ATTN: DON PELLETIER 1133 EAST CLIFF RD. BURNSVILLE, MN 55337	510(k) NO: K012262 PHONE NO : 952-890-1360	DEVICE: BAXTER AS40A, AS41 SYRINGE PUMP, MODEL N61WC SE DECISION MADE: 12-SEP-2001 510(k) STATEMENT
NATIONAL CUSTOM ENT., INC. IWC2 ATTN: DON PELLETIER 1133 EAST CLIFF RD. BURNSVILLE, MN 55337	510(k) NO: K012266 PHONE NO : 952-890-1360	DEVICE: SHERWOOD 224, 324 FEEDING PUMP & K524 INTRI-FLUSH, MODEL N7213 SE DECISION MADE: 12-SEP-2001 510(k) STATEMENT
NATS CORP. ATTN: RICHARD C LANZILLOTTO 30 NORTHPORT ROAD SOUND BEACH, NY 11789-1734	510(k) NO: K011820 PHONE NO : 631-744-0059	DEVICE: DENTORIUM CONVERTIBLE ACRYLIC SE DECISION MADE: 05-SEP-2001 510(k) STATEMENT
NEU COLL MODEL 1X,3X,6X (1,3 OR 6 STRIPS PER BOX) ATTN: ANNE WORDEN 2500 FABER PLACE PALO ALTO, CA 94303	510(k) NO: K000122 PHONE NO : 650-320-5789	DEVICE: COLLAGRAFT STRIP BONE GRAFT MATRIX (FOR USE AS A BONE FILLER), SE DECISION MADE: 20-SEP-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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NEUROSOFT, INC.  
ATTN: ELVIRA GARCIA  
5700 CROMO, SUITE 100  
EL PASO, TX 79912

510(k) NO: K011241  
PHONE NO : 915-845-5600

DEVICE: NEUROSOFT'S SOURCE  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K011821  
PHONE NO : 301-279-2899

DEVICE: MODIFICATION TO THE I.C.O.S SCREW  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

NEWDEAL S.A.  
ATTN: MORGANE GRENIER  
9109 COPENHAVER DRIVE  
POTOMAC, MD 20854

510(k) NO: K011875  
PHONE NO : 301-279-2899

DEVICE: MODIFICATION TO THE TAC' PIN  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

NEXAN LTD  
ATTN: DAVID L WEST  
1801 ROCKVILLE PIKE  
SUITE 300  
ROCKVILLE, MD 20852

510(k) NO: K010424  
PHONE NO : 301-272-3113

DEVICE: NEXAN SYSTEM, MODEL NX-301  
SE DECISION MADE: 04-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

NICHOLS INSTITUTE DIAGNOSTICS  
(REAGENTS, CONTROLS, AND SAMPLE DILUENT)  
ATTN: JIMMY WONG  
33051 CALLE AVIADOR  
SAN JUAN CAPISTRANO, CA 92675

510(k) NO: K011128  
PHONE NO : 949-240-5260

DEVICE: NICHOLS ADVANTAGE DIRECT RENIN (CALIBRATORS, CALIBRATION VERIF  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

NICOLET BIOMEDICAL, INC.  
ATTN: GARY SYRING  
800 LEVANGER LANE  
STOUGHTON, WI 53589

510(k) NO: K011818  
PHONE NO : 608-877-2635

DEVICE: STERILE EMG ELECTRODES  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

NICOLET BIOMEDICAL, INC.  
ATTN: GARY J SYRING  
800 LEVANGER LANE  
STOUGHTON, WI 53589

510(k) NO: K011823  
PHONE NO : 608-877-2635

DEVICE: BIOREHAB SYSTEM  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

NIHON KOHDEN AMERICA, INC.  
, MODEL BSM-2300A SERIES  
ATTN: BONNIE BISHOP  
90 ICON STREET  
FOOTHILL RANCH, CA 92610-1601

510(k) NO: K011918  
PHONE NO : 949-580-1555

DEVICE: NIHON KOHDEN BSM-2300A SERIES BEDSIDE MONITOR AND ACCESSORIES  
SE DECISION MADE: 12-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

NSI  
ATTN: GRETA M HOLS  
10565 LEE HIGHWAY  
SUITE 100  
FAIRFAX,, VA 22030

510(k) NO: K003620  
PHONE NO : 703-278-3953

DEVICE: NSI HEXED AND NON-HEXED IMPLANT SYSTEM  
SE DECISION MADE: 19-SEP-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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NUCLETRON CORP.  
ATTN: LISA DIMMICK  
7080 COLUMBIA GATEWAY DR.  
COLUMBIA, MD 21046-2133

510(k) NO: K012165  
PHONE NO : 410-312-4100

DEVICE: OLDELFT THORASCAN MODEL NUMBER 180T  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

OMNICARE DENTAL IMPLANT CENTER  
ATTN: FLOYD G LARSON  
4329 GRAYDON ROAD  
SAN DIEGO, CA 92130

510(k) NO: K000035  
PHONE NO : 858-792-1235

DEVICE: OMNICARE DENTAL IMPLANT SYSTEM  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

OPUS MEDICAL, INC.  
ATTN: MARK RITCHART  
27127 CALLE ARROYO, SUITE 1924  
SAN JUAN CAPISTRANO, CA 92675

510(k) NO: K012125  
PHONE NO : 949-234-0400

DEVICE: OPUS MAGNUM ANCHOR & INSERTER  
SE DECISION MADE: 17-SEP-2001  
510(k) STATEMENT

ORTHOGEN CORP.  
ATTN: ELAINE DUNCAN  
P.O. BOX 560  
STILLWATER, MN 55082

510(k) NO: K011403  
PHONE NO : 715-549-6035

DEVICE: SURGIPLASTER CALCIUM SULFATE HEMIHYDRATE  
SE DECISION MADE: 11-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ORIHOVITA, , INC.  
NGE  
ATTN: ANGIE IDE  
45 GREAT VALLEY PKWY.  
MALVERN, PA 19355

510(k) NO: K011087  
PHONE NO : 610-407-5231

DEVICE: ORIHOVITA PISTON SYRINGE OR IMBIBE BONE MARROW ASPIRATION SYRI  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

OSTEOIMPLANT TECHNOLOGY, INC.  
ATTN: SAM SON  
11201 PEPPER RD.  
HUNT VALLEY, MD 21031-1201

510(k) NO: K011774  
PHONE NO : 410-785-0700

DEVICE: R120 MODULAR TOTAL HIP SYSTEM  
SE DECISION MADE: 05-SEP-2001  
510(k) STATEMENT

OTOTECH, INC.  
ATTN: MICHAEL G FARROW  
1625 K STREET, NW  
SUITE 1000  
WASHINGTON, DC 20006

510(k) NO: K011338  
PHONE NO : 202-223-0157

DEVICE: OTO-CEM  
SE DECISION MADE: 13-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

P.T. HEALTHCARE GLOVINDO  
ATTN: ELLEN HUTAPEA  
JL. KOL. YOS SUDARSO K.M. 10  
KAWASAN INDUSRI MEDAN (KIM)  
MEDAN 10340,

510(k) NO: K010232  
PHONE NO : 620 616 50015

DEVICE: PRE-POWDERED NITRILE EXAMINATION GLOVES  
SE DECISION MADE: 21-SEP-2001  
510(k) STATEMENT

PACE MEDICAL  
AND 4825  
ATTN: ROBERT C MACE  
391 TOTTON POND RD.  
WALTHAM, MA 02451

510(k) NO: K011980  
PHONE NO : 781-890-5656

DEVICE: ADAPTER, PACING ANALYZER/UNIVERSAL PACING ADAPTER, MODELS 4820  
SE DECISION MADE: 12-SEP-2001  
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
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PACE MEDICAL ATTN: ROBERT C MACE 391 TOTTEN POND RD. WALTHAM, MA 02451	510(k) NO: K012392 PHONE NO : 781-890-5656	DEVICE: DISPOSABLE SURGICAL EXTENSION CABLE, MODEL 4255 AND MODEL 4260 SE DECISION MADE: 04-SEP-2001 510(k) STATEMENT
PADPRO LLC. ATTN: DANIEL KAMM P.O. BOX 7007 DEERFIELD, IL 60015	510(k) NO: K003548 PHONE NO : 847-374-1727	DEVICE: "PADPRO SYSTEM" DEFIBRILLATOR ELECTRODE ADAPTERS SE DECISION MADE: 04-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PALOMAR ATTN: MARCY MOORE 131 KELEKENT LANE CARY, NC 27511	510(k) NO: K010618 PHONE NO : 919-363-2432	DEVICE: PALOMAR DERMALUX PULSED LIGHT SYSTEM SE DECISION MADE: 10-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PARKELL, INC. ATTN: NELSON J GENDUSA 155 SCHMITT BLVD. P.O. BOX 376 FARMINGDALE, NY 11735	510(k) NO: K012360 PHONE NO : 631-249-1134	DEVICE: LC TEMPORARY FILLING SE DECISION MADE: 06-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PATTON MEDICAL CORP. ATTN: MICHAEL T PATTON 1000 WESTBANK DRIVE SUITE 5A200 AUSTIN, TX 78746	510(k) NO: K012150 PHONE NO : 512-916-4880	DEVICE: PATTON ENDO-BAG SE DECISION MADE: 20-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PAXMED INTERNATIONAL ATTN: FLOYD G LARSON 4329 GRAYDON ROAD SAN DIEGO, CA 92130	510(k) NO: K010467 PHONE NO : 858-792-1235	DEVICE: UNIVERSAL DENTAL COPING (UDC) SE DECISION MADE: 28-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PAXMED INTERNATIONAL ATTN: FLOYD G LARSON 4329 GRAYDON ROAD SAN DIEGO, CA 92130	510(k) NO: K011223 PHONE NO : 858-792-1235	DEVICE: QUANTUM VERSATILITY (QVS) DENTAL IMPLANT SYSTEM SE DECISION MADE: 20-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PLUS ORTHOPEDICS ATTN: HARMUT LOCH 6055 LUSK BLVD. SAN DIEGO, CA 92121-2700	510(k) NO: K011836 PHONE NO : 888-741-7587	DEVICE: MPF ACETABULAR CUP SE DECISION MADE: 07-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
POLYMER TECHNOLOGY CORP. ATTN: DEBRA L.B. KETCHUM 1400 N. GOODMAN STREET ROCHESTER, NY 14692	510(k) NO: K011945 PHONE NO : 716-338-8638	DEVICE: RIGID GAS PERMEABLE CONTACT LENS SOLUTION SE DECISION MADE: 12-SEP-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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PRECISION MEDICAL PRODUCTS, INC. ATTN: RONALD D WOLFE 12 INDUSTRIAL WAY DENVER, PA 17517	510(k) NO: K012515 PHONE NO : 717-335-3700	DEVICE: BIFURCATED VACCINATING NEEDLE SE DECISION MADE: 19-SEP-2001 510(k) STATEMENT
PREMIER DENTAL PRODUCTS CO. ATTN: BARRY HALE 7707 E. 201 TERR BELTON, MD 64012	510(k) NO: K012160 PHONE NO : 816-322-4641	DEVICE: COMPORE AF COMPOSITE CORE BUILD-UP MATERIAL, MODEL 3001408 SE DECISION MADE: 27-SEP-2001 510(k) STATEMENT
PRIME PACIFIC INTL. QUALITY PRODUCTS ATTN: OTHMAR VOGEL 145 RIVERSIDE DR. NORTH VANCOUVER,	510(k) NO: K000031 PHONE NO : 604 929 7019	DEVICE: AQUANET, MODEL EC 2000 SE DECISION MADE: 10-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
PROCTER & GAMBLE CO. SUPER & SUPER PLUS ATTN: MARK M ANDERSON 6110 CENTER HILL AVENUE CINCINNATI, OH 45224	510(k) NO: K011996 PHONE NO : 513-634-5196	DEVICE: TAMPAX PEARL SCENTED AND UNSCENTED TAMPONS - JUNIOR, REGULAR, SE DECISION MADE: 19-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
QINGDAO SHUANG DIE LATEX PRODUCTS ATTN: ELI J CARTER 1219 LITTLE CREEK ROAD DURHAM, NC 27713	510(k) NO: K012653 PHONE NO : 919-544-4098	DEVICE: MALE LATEX CONDOM SE DECISION MADE: 21-SEP-2001 510(k) STATEMENT
QUANTUM BIOENGINEERING, LTD. ATTN: RAUL R MENA 201 UNUNIVERSITY DR., SUITE 101 PLANTATION, FL 34134	510(k) NO: K991250 PHONE NO : 954-474-4707	DEVICE: QUANTUM VERSATILITY IMPLANT SYSTEM SE DECISION MADE: 20-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
QUANTUM BIOENGINEERING, LTD. ATTN: FLOYD G LARSON 201 UNUNIVERSITY DR., SUITE 101 PLANTATION, FL 34134	510(k) NO: K002241 PHONE NO : 858-792-1235	DEVICE: QUANTUM VERSATILITY (QVS) DENTAL IMPLANT SYSTEM SE DECISION MADE: 20-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
RADIANT INNOVATION, INC. ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD SUITE 200 GREAT NECK, NY 11021	510(k) NO: K011059 PHONE NO : 203-431-1511	DEVICE: INFARED EAR THERMOMETER, MODEL TH8 SERIES SE DECISION MADE: 17-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
RANDOX LABORATORIES, LTD. ATTN: P ARMSTRONG 55 DIAMOND RD. CRUMLIN, COUNTY ANTRIM,	510(k) NO: K011568 PHONE NO : 440 289 4422413	DEVICE: RANDOX LIPOPROTEIN SE DECISION MADE: 28-SEP-2001 510(k) STATEMENT

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

510(k) NO: K012318  
PHONE NO : 44 289 4422413

DEVICE: RANDOX THERAPEUTIC DRUG CALIBRATOR  
SE DECISION MADE: 12-SEP-2001  
510(k) STATEMENT

RANDOX LABORATORIES, LTD.  
ATTN: PAULINE ARMSTRONG  
ARDMORE, DIAMOND ROAD  
CRUMLIN,

510(k) NO: K012978  
PHONE NO : 441 849 422413

DEVICE: RANDOX GENTAMICIN  
SE DECISION MADE: 18-SEP-2001  
510(k) STATEMENT

REHABILICARE, INC.  
ICE; PROMAX-LIBRA, TENS DEVICE; PROMAX-MC, MICROCURRENT  
ATTN: EDWARD F VALDEZ  
1811 OLD HIGHWAY 8  
NEW BRIGHTON, MN 55112

510(k) NO: K011017  
PHONE NO : 612-638-0448

DEVICE: PROMAX-XP, TENS AND MICROCURRENT DEVICE; PROMAX-TENS, TENS DEV  
SE DECISION MADE: 24-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012042  
PHONE NO : 970-986-5345

DEVICE: KINETIC CANNULA  
SE DECISION MADE: 20-SEP-2001  
510(k) STATEMENT

RESTORATIVE HEALTH SVS, INC.  
ATTN: DAVID J BLOCH  
1301 K STREET, N.W.  
SUITE 1100-EAST TOWER  
WASHINGTON, DC 20005-3373

510(k) NO: K012007  
PHONE NO : 202-414-9209

DEVICE: RHS HELMET  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

RICHARD WOLF MEDICAL INSTRUMENTS  
CESSORIES, MODEL 2207.XXX  
ATTN: ROBERT L CASARSA  
353 CORPORATE WOODS PKWY.  
VERNON HILLS, IL 60061

510(k) NO: K011911  
PHONE NO : 847-913-1113

DEVICE: SUCTION PUMP FOR INTRACORPOREAL ULTRASOUND LITHOTRIPTER AND AC  
SE DECISION MADE: 17-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012371  
PHONE NO : 317-521-3831

DEVICE: TINA-QUANT TRANSFERRIN VER.2  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012393  
PHONE NO : 317-521-3831

DEVICE: TINA-QUANT TRANSFERRIN VER.2  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012397  
PHONE NO : 317-521-3544

DEVICE: URISYS 2400 URINE TEST STRIP  
SE DECISION MADE: 26-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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SCANDITRONIX MEDICAL AB  
ATTN: ALF OHMAN  
STALGATAN 14  
UPPSALA S-754 50,

510(k) NO: K011763  
PHONE NO : 461 818 0700

DEVICE: OMNIDOS  
SE DECISION MADE: 05-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SEEDLING ENTERPRISES. LLC.  
ATTN: DEBBIE IAMPETRO  
7 TIFFANY TRIAL  
HOPKINSON, MA 01748

510(k) NO: K012033  
PHONE NO : 508-435-9893

DEVICE: MULTIFUNCTION ENDOSCOPIC INSTRUMENT  
SE DECISION MADE: 20-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SEMPERMED USA, INC.  
TAINS 50 MICROGRAMS OR LESS OF TOTAL WATER EXTRACTABLE PRO  
ATTN: KATIE LEVINSON  
30798 US HWY. 19 NORTH  
PALM HARBOR, FL 34684

510(k) NO: K011407  
PHONE NO : 727-787-7250

DEVICE: LATEX POWDER-FREE EXAMINATION GLOVES BLUE, POLYMER COATED, CON  
SE DECISION MADE: 11-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SENORX, INC.  
ATTN: AMY BOUCLY  
11 COLUMBIA, SUITE A  
ALISO VIEJO, CA 92656

510(k) NO: K012004  
PHONE NO : 949-362-4800

DEVICE: EASY GUIDE ELECTROSURGICAL ACCESS DEVICE  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SENORX, INC.  
F GENERATOR CABLE  
ATTN: AMY BOUCLY  
11 COLUMBIA, SUITE A  
ALISO VIEJO, CA 92656

510(k) NO: K012023  
PHONE NO : 949-362-4800

DEVICE: ANCHOR GUIDE LESION LOCALIZATION DEVICE; ANCOR GUIDE HOLDER; R  
SE DECISION MADE: 12-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SENORX, INC.  
ATTN: AMY BOUCLY  
11 COLUMBIA, SUITE A  
ALISO VIEJO, CA 92656

510(k) NO: K012799  
PHONE NO : 949-362-4800

DEVICE: ES-2000 SHAPE SELECT ELECTROSURGICAL SCALPEL  
SE DECISION MADE: 04-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SGMP CO., LTD.  
UBERRY SCENTED AND PROTEIN CONTENT CLAIM (50 MICROGRAMS O  
ATTN: JANNA P TUCKER  
198 AVENUE DE LA D'EMERALD  
SPARKS, NV 89434

510(k) NO: K012857  
PHONE NO : 775-342-2612

DEVICE: NON-STERILE POWDER FREE PURPLE LATEX EXAMINATION GLOVE WITH BL  
SE DECISION MADE: 21-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SGMP CO., LTD.  
EIN LABELING CLAIM (<50UG/G)  
ATTN: JANNA P TUCKER  
198 AVENUE DE LA D'EMERALD  
SPARKS, NV 89434

510(k) NO: K012860  
PHONE NO : 775-342-2612

DEVICE: POWDER-FREE LATEX EXAM GLOVES WITH CHOCOLATE SCENTING AND PROT  
SE DECISION MADE: 21-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SGMP CO., LTD.  
AND PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)  
ATTN: JANNA TUCKER  
198 AVENUE DE LA D'EMERALD  
SPARKS, NV 89434

510(k) NO: K012863  
PHONE NO : 775-342-2612

DEVICE: NON-STERILE POWDER FREE LATEX EXAMINATION GLOVES WITH VANILLA  
SE DECISION MADE: 21-SEP-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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SHEN WEI (USA), INC. 510(k) NO: K011044  
MICROGRAMS OR LESS OF TOTAL WATER EXTRACTABLE PROTEIN PER  
ATTN: BELLE L CHOU PHONE NO : 510-429-8692  
2845 WHIPPLE RD.  
UNION CITY, CA 94587

DEVICE: TEXTURED POWDER-FREE LATEX EXAMINATION GLOVES WITH CONTAINS 50

SE DECISION MADE: 10-SEP-2001  
510(k) STATEMENT

SHEN WEI (USA), INC. 510(k) NO: K011045  
OGRAMS OR LESS OF TOTAL WATER EXTRACTABLE PROTEIN PER GRAM  
ATTN: BELLE CHOU PHONE NO : 520-845-0023  
2845 WHIPPLE RD.  
UNION CITY, CA 94587

DEVICE: TEXTURED POWDER-FREE LATEX EXAMINATION GLOVES CONTAINS 50 MICR

SE DECISION MADE: 11-SEP-2001  
510(k) STATEMENT

SHEN WEI (USA), INC. 510(k) NO: K011961  
S E PH5.5  
ATTN: BELLE L CHOU PHONE NO : 510-429-8692  
2845 WHIPPLE RD.  
UNION CITY, CA 94587

DEVICE: POWDER-FREE BUTADIENE COPOLYMER EXAM GLOVES WITH ALOE, VITAMIN

SE DECISION MADE: 26-SEP-2001  
510(k) STATEMENT

SHIELD GLOVES MANUFACTURER (M) SDN510(k) NO: K011613  
EXAMINATION GLOVE  
ATTN: JANNA P TUCKER PHONE NO : 775-342-2612  
198 AVENUE DE LA D'EMERALD  
SPARKS, NV 89434-9550

DEVICE: POWDER-FREE GREEN "BARRIER-PRO" SYNTHETIC BUTADIENE COPOLYMER

SE DECISION MADE: 17-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SHIJIAZHANG BRILLIANCE PLASTIC CO510(k) NO: K012711  
ATTN: HUAN CHUNG LI PHONE NO : 978-436-9980  
17A STERLING ROAD  
NORTH BILLERICA, MA 01862

DEVICE: DISPOSABLE POWDER FREE VINYL PATIENT EXAMINATION GLOVES

SE DECISION MADE: 18-SEP-2001  
510(k) STATEMENT

SIEMENS MEDICAL CORP. 510(k) NO: K012202  
ATTN: JAMIE YIEH PHONE NO : 732-321-4625  
186 WOOD AVE. SOUTH  
ISELIN, NJ 08830

DEVICE: NUMARIS 4VA15A  
SE DECISION MADE: 27-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SMART GLOVE CORP. SDN BHD 510(k) NO: K011066  
LABELING CLAIM (100 MICROGRAMS OR LESS)  
ATTN: NG-YEW SOON PHONE NO : 603 391 6100  
LOT 6487 BATU 5 3/4  
JALAN KAPAR  
KLANG SELANGOR,

DEVICE: STERILE LATEX SURGICAL GLOVES (POWDERED) WITH PROTEIN CONTENT

SE DECISION MADE: 11-SEP-2001  
510(k) STATEMENT

SMART GLOVE CORP. SDN BHD 510(k) NO: K012479  
ATTN: FOO KHON PU PHONE NO : 603 329 16100  
LOT 6487 BATU 5 3/4  
JALAN KAPAR  
KLANG SELANGOR,

DEVICE: STERILE NITRILE SURGICAL GLOVES (POWDERED)  
SE DECISION MADE: 26-SEP-2001

510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
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SMITH & NEPHEW, INC.  
ATTN: STEVEN JACKSON  
3600 NW 138TH STREET  
OKLAHOMA CITY, OK 73134

510(k) NO: K011944  
PHONE NO : 405-936-3085

DEVICE: DYONICS VISION 635 DIGITAL CAPTURE SYSTEM, MODEL 7209088  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SODEM SYSTEMS  
ATTN: CAROLE BURNIER  
110 CH. DU PONT DU CENIENAIRE  
GENEVA,

510(k) NO: K012456  
PHONE NO : 41 22 7949696

DEVICE: SODEM HIGH SPEED SYSTEM (ELECTRIC) (EAR, NOSE, AND THROAT)  
SE DECISION MADE: 21-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

ST. JUDE MEDICAL  
ATTN: KIRK S HONOUR  
14901 DEVEAU PL.  
MINNETONKA, MN 55345-2126

510(k) NO: K012922  
PHONE NO : 952-352-9737

DEVICE: ULTRAFLEX EV HEMOSTASIS INTRODUCER  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012845  
PHONE NO : 650-949-0470

DEVICE: SIMPLICITY SOFT QD MICRO INFUSION SET  
SE DECISION MADE: 14-SEP-2001  
510(k) STATEMENT

STRYKER ENDOSCOPY  
ATTN: ALISA MILLER  
2590 WALSH AVE.  
SANITA CLARA, CA 95051

510(k) NO: K012270  
PHONE NO : 408-567-9100

DEVICE: STRYKER CROSS-PINNED INTERFERENCE SCREW SYSTEM  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SULZER DENTAL, INC.  
ATTN: FOSTER BOOP  
1900 ASTON AVE.  
CARLSBAD, CA 92008-7308

510(k) NO: K012055  
PHONE NO : 760-431-9515

DEVICE: 3.25MM SPLINE TWIST IMPLANT  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K011806  
PHONE NO : 651-697-2018

DEVICE: PROTEGE SELF-EXPANDING NITINOL STENT WITH STARPORT DELIVERY TE  
SE DECISION MADE: 07-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SULZER ORTHOPEDICS, INC.  
ATTN: BRUCE WALDON  
9900 SPECTRUM DR.  
AUSTIN, TX 78717

510(k) NO: K011954  
PHONE NO : 512-432-9482

DEVICE: SULZER ORTHOPEDICS ALLEGRETTO UNICOMPARTIMENTAL KNEE  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SULZER SPINE-TECH  
ATTN: KRISTYN M BENSON  
7375 BUSH LAKE RD.  
MINNEAPOLIS, MN 55439-2027

510(k) NO: K012173  
PHONE NO : 952-830-6273

DEVICE: DEVICE MODIFICATION OF SILHOUETTE SPINDAL FIXATION SYSTEM  
SE DECISION MADE: 28-SEP-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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SUTURA, INC.  
ATTN: JAMES BONDS  
17080 NEWHOPE ST.  
FOUNTAIN VALLEY, CA 92708

510(k) NO: K012865  
PHONE NO : 714-437-9801

DEVICE: SUPERSTITCH VASCULAR SUTURING DEVICE  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012082  
PHONE NO : 714-516-7484

DEVICE: OPTIBOND SOLO PLUS ACTIVATOR  
SE DECISION MADE: 20-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SYBRON DENTAL SPECIALTIES, INC.  
ATTN: COLLEEN BOSWELL  
1717 WEST COLLINS AVENUE  
ORANGE, CA 92667

510(k) NO: K012405  
PHONE NO : 714-516-7484

DEVICE: EXTRUDE MODIFIED  
SE DECISION MADE: 04-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)  
ATTN: MATTHEW M HULL  
1690 RUSSELL RD.  
PAOLI, PA 19301

510(k) NO: K011815  
PHONE NO : 610-647-9700

DEVICE: SYNTHES LCP PROXIMAL HUMERUS PLATES  
SE DECISION MADE: 06-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)  
ATTN: BONNIE J SMITH  
1690 RUSSELL ROAD  
POST OFFICE BOX 1766  
PAOLI, PA 19301

510(k) NO: K011857  
PHONE NO : 610-647-9700

DEVICE: SYNTHES (USA) TROCHANTERIC FIXATION NAIL (TFN) SYSTEM  
SE DECISION MADE: 12-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012114  
PHONE NO : 610-647-9700

DEVICE: SYNTHES LOCKING DISTAL RADIUS PLATING SYSTEM  
SE DECISION MADE: 28-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

SYSMEX CORP.  
ATTN: CHRIS STUKEL  
GILMER ROAD  
6699 RFD  
LONG GROVE, IL 60047-9596

510(k) NO: K012372  
PHONE NO : 847-726-3523

DEVICE: SYSMEX UF-50  
SE DECISION MADE: 28-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

TE ME NA S.A.R.L.  
ATTN: JOE HARMS  
390 SCARLET BLVD  
OLDSMAR, FL 34677

510(k) NO: K990323  
PHONE NO : 813-818-8705

DEVICE: TE ME NA POLYSTIM NERVE STIMULATOR  
SE DECISION MADE: 28-SEP-2001  
510(k) STATEMENT

TELEMEDIC SYSTEMS, INC.  
ATTN: STENEN CHERNOFF  
P.O. BOX 3515  
REDMOND, WA 98073-3515

510(k) NO: K010732  
PHONE NO : 425-861-8262

DEVICE: VITALINK 1200 MOBILE VITAL SIGNS SYSTEMS (VL 1200 SYSTEM)  
SE DECISION MADE: 27-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-SEP-2001 THROUGH 30-SEP-2001

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TERARECON, INC.  
ATTN: DAVID W SCHLERF  
200 GREGORY LANE  
SUITE C-100  
PLEASANT HILL, CA 94523-3389

510(k) NO: K012086  
PHONE NO : 925-356-2640

DEVICE: AQUARIUSNET SERVER  
SE DECISION MADE: 13-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

THE OLYMPUS OPTICAL CO.  
ATTN: LAURA STORMS-TYLER  
TWO CORPORATE CENTER DRIVE  
MELVILLE, NY 11747

510(k) NO: K012074  
PHONE NO : 631-844-5688

DEVICE: XBO1-824-18/19/20 BIOPSY FORCEPS  
SE DECISION MADE: 25-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K011854  
PHONE NO : 202-261-1040

DEVICE: TOKUYAMA M-BOND  
SE DECISION MADE: 04-SEP-2001

510(k) SUMMARY AVAILABLE FROM FDA

TOSOH MEDICS, INC.  
ATTN: LOIS NAKAYAMA  
347 OYSTER POINT BLVD.,  
SUITE 201  
SOUTH SAN FRANCISCO, CA 94080

510(k) NO: K011434  
PHONE NO : 800-248-6764

DEVICE: G7 AUTOMATED HPLC ANALYZER  
SE DECISION MADE: 18-SEP-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: K012565  
PHONE NO : 800-216-9036

DEVICE: SENSITITRE HAEMOPHILUS/STREPTOCOCCUS PNEUMONIAE (HP) MIC PLATE  
SE DECISION MADE: 12-SEP-2001  
510(k) STATEMENT

TIK HEALTHCARE LTD.  
ATTN: ELI J CARTER  
1219 LITTLE CREEK ROAD  
DURHAM, NC 27713

510(k) NO: K012067  
PHONE NO : 919-544-4098

DEVICE: CLINCARE LATEX SURGEON'S GLOVE  
SE DECISION MADE: 17-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

UNITED STATES SURGICAL, A DIVISION  
ATTN: CHESTER MOCOY  
150 GLOVER AVE.  
NORWALK, CT 06856

510(k) NO: K012539  
PHONE NO : 203-845-1390

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

UNIVERSAL IMPLANT SYSTEMS, INC.  
ATTN: FLOYD G LARSON  
4329 GRAYDON ROAD  
SAN DIEGO, CA 92130

510(k) NO: K011574  
PHONE NO : 858-792-1235

DEVICE: UNIPLANT DENTAL IMPLANT SYSTEM  
SE DECISION MADE: 28-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

VANGUARD MEDICAL CONCEPTS, INC.  
ATTN: MIKE SAMMON  
5307 GREAT OAK DR.  
LAKELAND, FL 33815

510(k) NO: K011800  
PHONE NO : 863-683-8680

DEVICE: VANGUARD REPROCESSED ELECTRIC BIOPSY FORCEPS  
SE DECISION MADE: 27-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRI SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS  
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VENTILAB CORP.  
ATTN: MARGE WALLS-WALKER  
2934 HWY. 601 NORTH  
MOCKSVILLE, NC 27028

510(k) NO: K012842  
PHONE NO : 800-593-4654

DEVICE: V\*CARE MANUAL RESUSCITATOR  
SE DECISION MADE: 18-SEP-2001  
510(k) STATEMENT

VYGON CORP.  
ATTN: ROBERT SCHIFF  
1129 BLOOMFIELD AVE.  
WEST CALDWELL, NJ 07006

510(k) NO: K010913  
PHONE NO : 201-227-1830

DEVICE: VYGON SPLIT CANNULA INTRODUCER  
SE DECISION MADE: 28-SEP-2001  
510(k) STATEMENT

W.L. GORE & ASSOCIATES, INC  
ATTN: R. LARRY PRATT  
3750 WEST KILTIE LN.  
FLAGSTAFF, AZ 86002-0900

510(k) NO: K012098  
PHONE NO : 520-779-2771

DEVICE: PRECLUDE PERICARDIAL MEMBRANE  
SE DECISION MADE: 20-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

WIENER LABORATORIES S.A.I.C.  
ATTN: VIVIANA CETOLA  
2944 RIOBAMBA  
ROSARIO,

510(k) NO: K012260  
PHONE NO : 54 341 4329191

DEVICE: WIENER LAB. UREA UV CINETICA AA  
SE DECISION MADE: 19-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

WIENER LABORATORIES S.A.I.C.  
CAT 1009300  
ATTN: VIVIANA CETOLA  
2944 RIOBAMBA  
ROSARIO,

510(k) NO: K012329  
PHONE NO : 543 414 329191

DEVICE: WIENER LAB. ALBUMINA AA, MODELS 6X60 ML CAT N 1690008, 6X120 ML  
SE DECISION MADE: 21-SEP-2001  
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012793  
PHONE NO : 219-372-4219

DEVICE: MODIFICATION TO: ALUMINA CERAMIC FEMORAL HEADS, MODEL 6418 SER  
SE DECISION MADE: 06-SEP-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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TOTAL 510(k)s THIS PERIOD	282
TOTAL WITH SUMMARIES	217
TOTAL WITH STATEMENTS	65