"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
138 MEDICAL SUPPLIES, INC. DEL E-188 ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD., SUITE 200 GREAT NECK, NY 11021	510(k) NO: K000741 PHONE NO : 203-431-1511	DEVICE: EMS JUMPER II DUAL CHANNEL NEUROMUSCULAR STIMULATOR SYSTEM, MC SE DECISION MADE: 24-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
3D LINE USA, INC. ATTN: KAREN H RIGAMONTI 2807 OLD COURT ROAD BALTIMORE, MD 21208	510(k) NO: K011255 PHONE NO : 410-580-1730	DEVICE: 3D LINE STEROTACTIC HARDWARE ACCESSORIES SE DECISION MADE: 20-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
3M CO. ATTN: LINDA JOHNSEN 3M CENTER, BUILDING 275-5W-06 ST. PAUL, MN 55144-1000	510(k) NO: K003723 PHONE NO : 651-737-4376	DEVICE: 3M LITTMANN SE DECISION MADE: 27-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
3M CO. ATTN: SCOTT ERICKSON 3M CENTER, BLDG. 260-2B-12 ST PAUL, MN 55144	510(k) NO: K010781 PHONE NO : 651-736-9883	DEVICE: 3M ESPE HAUR SE DECISION MADE: 13-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
3M CO. ATTN: KAREN O'MALLEY 3M CENTER, BLDG. 260-2B-12 ST PAUL, MN 55144	510(k) NO: K011167 PHONE NO : 651-736-7326	DEVICE: XSE SE DECISION MADE: 17-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
3M CO. ATTN: KAREN O'MALLEY 3M CENTER, BLDG. 260-2B-12 ST PAUL, MN 55144	510(k) NO: K011200 PHONE NO : 651-736-7326	DEVICE: GILB, MODEL 8010 SE DECISION MADE: 14-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
3T MEDICAL SYSTEMS, LLC. ATTN: TIMOTHY J SIMMONS 6770 PINE WAY DRIVE TROY, MI 48098	510(k) NO: K001245 PHONE NO : 248-879-6968	DEVICE: 3T L. V. CONTROL VALVE SE DECISION MADE: 15-AUG-2001 510(k) STATEMENT

945-0120

LST/10

<GENX> INTL., INC. ATTN: MICHAEL D CECCHI 170 FORT PATH RD., UNIT 14 MADISON, CT 06443	510(k) NO: K010183 PHONE NO : 800-966-6453	DEVICE: GLOBAL BY <GENX> BLASTOCYST MEDIA SE DECISION MADE: 02-MAY-2001 510(k) STATEMENT
A & A MEDICAL, INC. ATTN: JIHAD MANSOUR 9370 INDUSTRIAL TRACE ALPHARETTA, GA 30004-3383	510(k) NO: K003949 PHONE NO : 770-343-8400	DEVICE: TACKER, MODEL R65-933 SE DECISION MADE: 25-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
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 & A MEDICAL, INC. MODEL R65-985-1 ATTN: JIHAD (JAY) MANSOUR 9370 INDUSTRIAL TRACE ALPHARETTA, GA 30004-3383	510(k) NO: K010510 PHONE NO : 770-343-8400	DEVICE: BALLOON CANNULA, SHORT, MODEL R65-985; BALLOON CANNULA, LONG, SE DECISION MADE: 16-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
A & A MEDICAL, INC. -995-1, R65-995-2, R65-997, R65-997-1 ATTN: JIHAD MANSOUR 9370 INDUSTRIAL TRACE ALPHARETTA, GA 30004-3383	510(k) NO: K010789 PHONE NO : 770-343-8400	DEVICE: CANNULA, SURGICAL GENERAL & PLASTIC SURGERY, MODELR65-995, R65 SE DECISION MADE: 27-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
A & A MEDICAL, INC. ATTN: JIHAD (JAY) MANSOUR 9370 INDUSTRIAL TRACE ALPHARETTA, GA 30004-3383	510(k) NO: K011512 PHONE NO : 770-343-8400	DEVICE: MMODIFICATION TO LAMINARIA SE DECISION MADE: 09-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
A & A MEDICAL, INC. ATTN: JAY MANSOUR 9370 INDUSTRIAL TRACE ALPHARETTA, GA 30004-3383	510(k) NO: K013437 PHONE NO : 770-343-8400	DEVICE: SF SH CATHETER, MODEL R65-945 SE DECISION MADE: 19-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
A & A MEDICAL, INC. L R65-948 ATTN: JAY MANSOUR 9370 INDUSTRIAL TRACE ALPHARETTA, GA 30004-3383	510(k) NO: K013491 PHONE NO : 770-343-8400	DEVICE: HSG CATHETER SET, 5F MODEL RGS0947, HSG CATHETER SET, 7F, MODE SE DECISION MADE: 19-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
A & D ENGINEERING, INC. ATTN: JERRY WANG 1555 MC CANDLESS DR. MILPITAS, CA 95035	510(k) NO: K002061 PHONE NO : 408-263-5333	DEVICE: A&D MEDICAL TM-2550/TM-2551/TM-2560 VITAL SENSOR MONITOR SE DECISION MADE: 19-JAN-2001 510(k) STATEMENT

A & D ENGINEERING, INC. M-2655VP ATTN: JERRY WANG 1555 MC CANDLESS DR. MILPITAS, CA 95035	510(k) NO: K010828 PHONE NO : 408-263-5333	DEVICE: DIGITAL BLOOD PRESSURE MONITORS, MODELS TM-2655, TM-2655P, & T SE DECISION MADE: 29-MAR-2001 510(k) STATEMENT
A & D ENGINEERING, INC. ATTN: JERRY WANG 1555 MC CANDLESS DR. MILPITAS, CA 95035	510(k) NO: K012013 PHONE NO : 408-263-5333	DEVICE: LIFESOURCE MODELS UA-787, UA 787PC, UA-787T SE DECISION MADE: 13-JUL-2001 510(k) STATEMENT
A-DEC, INC. ATTN: LOVENA STANDRIDGE 2601 CRESTVIEW DR. NEWBERG, OR 97132-9257	510(k) NO: K010127 PHONE NO : 503-538-9471	DEVICE: W & H ASSISTINA SE DECISION MADE: 05-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
A-MED SYSTEMS, INC. #CP-1H ATTN: CYNTHIA G ROYSTER 2491 BOATMAN AVE. WEST SACRAMENTO, CA 95691	510(k) NO: K013393 PHONE NO : 916-375-7400	DEVICE: HEPARIN COATED MINIATURE CENTRIFUGAL BYPASS PUMP SYSTEM;MODEL SE DECISION MADE: 09-NOV-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
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
AB ARDENT ATTN: CLYDE E INGERSOLL 54 RIVERVIEW AVE TONAWANDA, NY 14150-5260	510(k) NO: K011801 PHONE NO : 716-693-6591	DEVICE: FUTURA TOPCAP NON GAMMA-2 SE DECISION MADE: 16-AUG-2001 510(k) STATEMENT
AB BIODISK ATTN: ANNE BOLMSTROM DALVAGEN 10 SOLNA,	510(k) NO: K010363 PHONE NO : 46 873 00760	DEVICE: ETEST MEROPENEM SE DECISION MADE: 09-APR-2001 510(k) STATEMENT

ABAXIS, INC. ATTN: AMY LEVIN 3240 WHIPPLE ROAD UNION CITY, CA 94587	510(k) NO: K010670 PHONE NO : 510-675-6500	DEVICE: PICCOLO CHLORIDE TEST SYSTEM SE DECISION MADE: 26-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ABBOTT LABORATORIES ATTN: THOMAS P SAMPONGA D-389, AP30 ABBOTT PARK N.CHICAGO, IL 60064	510(k) NO: K002717 PHONE NO : 847-935-3715	DEVICE: STERILE PISTON SYRINGE SE DECISION MADE: 08-JAN-2001 510(k) STATEMENT
ABBOTT LABORATORIES OLOGY ATTN: JANET CONNOLLY 4-A CROSBY DR. BEDFORD, MA 01730-1402	510(k) NO: K010553 PHONE NO : 781-276-6230	DEVICE: PRECISION XTRA BLOOD GLUCOSE TEST STRIP WITH TRUEMEASURE TECHN SE DECISION MADE: 18-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ABBOTT LABORATORIES ATTN: FRANK POKROP DEPT.37K, BUILDING AP30 200 ABBOTT PARK ROAD ABBOTT PARK, IL 60064-6157	510(k) NO: K010924 PHONE NO : 847-937-8473	DEVICE: MODIFICATION TO PLUM XL INFUSION PUMP SE DECISION MADE: 06-APR-2001 510(k) STATEMENT
ABBOTT LABORATORIES ATTN: JOHN DEAN 5440 PATRICK HENRY DR. SANTA CLARA, CA 95054	510(k) NO: K010953 PHONE NO : 408-567-3430	DEVICE: CELL-DYN 4000 IMMUNO T-CELL (CD3/4/8) ASSAY SE DECISION MADE: 06-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ABBOTT LABORATORIES ATTN: FRANK POKROP 200 ABBOTT PARK ROAD ABBOTT PARK, IL 60064	510(k) NO: K011096 PHONE NO : 847-937-8473	DEVICE: ABBOTT ACCLAIM ENCORE, MODEL 12237 SE DECISION MADE: 01-MAY-2001 510(k) STATEMENT
ABBOTT LABORATORIES ROTATOR, CATH LAB KIT ATTN: THOMAS P SAMPOGNA DEPT. 389, BLDG. AP30 200 ABBOTT PARK ROAD ABBOTT PARK, IL 60064-6157	510(k) NO: K011217 PHONE NO : 847-935-3715	DEVICE: CLEAR OR BRAIDED CONTRAST MEDIA INJECTION LINE WITH OR WITHOUT SE DECISION MADE: 16-MAY-2001 510(k) STATEMENT
ABBOTT LABORATORIES ATTN: FRANK POKROP DEPT 37K BLDG AP30 200 ABBOTT PARK ROAD ABBOTT PARK, IL 60064	510(k) NO: K011442 PHONE NO : 847-937-8473	DEVICE: ABBOTT PLUM A+INFUSION PUMP, MODEL 11971 SE DECISION MADE: 05-JUN-2001 510(k) STATEMENT

ABBOTT LABORATORIES ATTN: JOHN DEAN 5440 PATRICK HENRY DR. SANTA 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
ABBOTT LABORATORIES ATTN: ALICIA SIMPSON 1920 HURD DRIVE, MS 8-21 IRVING, TX 75038	510(k) NO: K013538 PHONE NO : 972-518-7864	DEVICE: ETHANOL SE DECISION MADE: 14-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
ABLE SOFTWARE CORP. ATTN: YECHENG WU 5 APPLETREE LANE LEXINGTON, MA 02420-2406	510(k) NO: K003746 PHONE NO : 781-862-2804	DEVICE: 3D-DOCTOR SE DECISION MADE: 13-MAR-2001 510(k) STATEMENT
ACCELERATED REHAB DESIGNS, INC. ATTN: RANDALL POTTER 32025 INDUSTRIAL PARK DR. PINEHURST, TX 77362	510(k) NO: K010011 PHONE NO : 281-356-1950	DEVICE: TE-2000 POWER TILT/POWER ELEVATING SEAT COMBINATION SYSTEM SE DECISION MADE: 12-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACCELERATED REHAB DESIGNS, INC. ATTN: RANDALL POTTER 32025 INDUSTRIAL PARK DR. PINEHURST, TX 77362	510(k) NO: K012281 PHONE NO : 281-356-1950	DEVICE: TRS-2000 POWER TILT/POWER RECLINE SYSTEM SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACCUFAST, INC. ATTN: DON LOGAN 251 CREE CRESCENT WINNIPEG, MANITOBA,	510(k) NO: K011752 PHONE NO : 204 837 8366	DEVICE: GOVAN+ WHEELCHAIR AND DOCKING ACCESSORY SE DECISION MADE: 28-JUN-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
ACCUMETRICS, INC. ATTN: RHONDA MOE 3985 SORRENTO VALLEY BLVD SAN DIEGO, CA 92121	510(k) NO: K011337 PHONE NO : 858-404-8238	DEVICE: ULTEGRA SYSTEM RAPID PLATELET FUNCTION ASSAY (RPFA) SE DECISION MADE: 16-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACCURAY, INC. ATTN: E. BRUCE FLOYD 570 DEL REY AVE. SUNNYVALE, CA 94085	510(k) NO: K011024 PHONE NO : 408-522-3740	DEVICE: CYBERKNIFE SYSTEM SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
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

ACIST MEDICAL SYSTEMS, INC. ATTN: CARL M BEAURLINE 7450 FLYING CLOUDS DR. SUITE 150 EDEN PRAIRIE, MN 55344	510(k) NO: K010390 PHONE NO : 612-941-3507	DEVICE: ACIST ANGIOGRAPHIC INJECTION SYSTEM, MODEL R2000-CMS SE DECISION MADE: 09-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACKARD LABORATORIES ATTN: RICHARD HETTENBACH 70 JACKSON DR. P.O. BOX 1085 CRANFORD, NJ 07016	510(k) NO: K013972 PHONE NO : 908-276-6290	DEVICE: H/S ELLIPTOSPHERE CATHETER SET, MODEL 61-4005 SE DECISION MADE: 17-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES CO. ATTN: ROBERT HUDAK 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K010582 PHONE NO : 858-535-2030	DEVICE: ACON STREP A RAPID TEST STRIP SE DECISION MADE: 07-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. P MARIJUANA TEST DEVICE (URINE) ATTN: NORA C.R. YORK 11175 FLINTKOTE AVE., #F SAN DIEGO, CA 92121	510(k) NO: K003557 PHONE NO : 858-535-2030	DEVICE: ACON THC ONE STEP MARIJUANA TEST STRIP(URINE);ACON THC ONE STE SE DECISION MADE: 15-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. E TEST DEVICE ATTN: ROBERT HUDAK 4108 SORRENTO VALLEY BLVD SAN DIEGO, CA 92121	510(k) NO: K010841 PHONE NO : 858-535-2030	DEVICE: ACON COC ONE STEP COCAINE TEST STRIP, ACON COC ONE STEP COCAIN SE DECISION MADE: 09-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. S TEST DEVICE ATTN: EDWARD TUNG 4104 SORRENTO VALLY BLVD. SAN DIEGO, CA 92121	510(k) NO: K011353 PHONE NO : 858-535-2030	DEVICE: ACON OPI ONE STEP OPIATES TEST STRIP, ACON OPI ONE STEP OPIATE SE DECISION MADE: 30-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. TEP METHAMPHETAMINE TEST DEVICE ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K011672 PHONE NO : 858-535-2030	DEVICE: ACON MAMP ONE STEP METHAMPHETAMINE TEST STRIP, ACON MAMP ONE S SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. PHETAMINE TEST DEVICE ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K011673 PHONE NO : 858-535-2030	DEVICE: ACON AMP ONE STEP AMPHETAMINE TEST STRIP, ACON AMP ONE STEP AM SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA

ACON LABORATORIES, INC. PHENCYCLIDINE TEST DEVICE ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K011730 PHONE NO : 858-535-2030	DEVICE: ACON PCP ONE-STEP PHENCYCLIDINE TEST STRIP, ACON PCP ONE-STEP SE DECISION MADE: 09-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K012215 PHONE NO : 858-535-2030	DEVICE: QUIK-CHECK HOME PREGNANCY TEST SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. ATTN: FRAN WHITE 163 CABOT STREET BEVERLY, MA 01915	510(k) NO: K012252 PHONE NO :	DEVICE: QUIK-CHECK OVULATION PREDICTOR SE DECISION MADE: 24-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
ACON LABORATORIES, INC. ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K012595 PHONE NO : 858-535-2030	DEVICE: ACON MTD ONE STEP METHADONE TEST STRIP AND TEST DEVICE SE DECISION MADE: 15-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. ARBITURATES TEST DEVICE ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K012824 PHONE NO : 858-535-2030	DEVICE: ACON BAR ONE STEP BARBITURATES TEST STRIP, ACON BAR ONE STEP B SE DECISION MADE: 09-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACON LABORATORIES, INC. DEVICE ATTN: EDWARD TUNG 4108 SORRENTO VALLEY BLVD. SAN DIEGO, CA 92121	510(k) NO: K013380 PHONE NO : 858-535-2030	DEVICE: ACON MOP ONE STEP OPIATE TEST STRIP, ACON MOP STEP OPIATE TEST SE DECISION MADE: 18-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
ACRYMED, INC. ATTN: BRUCE GIBBINS 12232 SW GARDEN PLACE PORTLAND, OR 97223	510(k) NO: K011994 PHONE NO : 503-624-9830	DEVICE: ACRYDERM SILVER ANTIMICROBIAL WOUND GEL MODEL# A-002101 SE DECISION MADE: 08-NOV-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

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

ACTIVATOR METHODS INTERNATIONAL, L
ATTN: ARLAN W FUHR
3714 EAST INDIAN SCHOOL RD.
PHOENIX, AZ 85018

510(k) NO: K003185
PHONE NO : 602-224-0220

DEVICE: FS ACTIVATOR III
SE DECISION MADE: 20-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACTIVE CORP.
ATTN: KAREN SIEGEL
15 MAIN STREET
CASTINE, ME 04421-1000

510(k) NO: K010587
PHONE NO : 207-326-9100

DEVICE: ACTIVEECG
SE DECISION MADE: 16-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACUEITY, INC.
ATTN: MARYBETH FECTEAU
15 INDUSTRIAL PARK EAST
OXFORD, MA 01540

510(k) NO: K011189
PHONE NO : 508-987-6612

DEVICE: VIADUCT MICROENDOSCOPE AND ACCESSORIES
SE DECISION MADE: 16-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACUMED, INC.
ATTN: SHARI JEFFERS
10950 S.W. 5TH ST., SUITE 170
BEAVERTON, OR 97005

510(k) NO: K012655
PHONE NO : 503-627-9957

DEVICE: CONGRUENT BONE PLATE SYSTEM
SE DECISION MADE: 07-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACUMED, INC.
ATTN: SHARI JEFFERS
10950 S.W. 5TH ST., SUITE 170
BEAVERTON, OR 97005

510(k) NO: K013616
PHONE NO : 503-627-9957

DEVICE: POLARUS CAP SCREW
SE DECISION MADE: 19-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACUSON CORP.
ATTN: HOWARD M HOLSTEIN
555 13TH ST., N.W.
WASHINGTON, DC 20004-1109

510(k) NO: K010950
PHONE NO : 202-637-5813

DEVICE: CYPRESS SYSTEM
SE DECISION MADE: 27-JUN-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

ACUSUPPLY, INC.
ATTN: FERES DAGER
3801 NE 207TH STR. SUITE 501
AVENTURA, FL 33180

510(k) NO: K011247
PHONE NO : 305-932-9413

DEVICE: HOLY DRAGON STERILE ACUPUNCTURE NEEDLE FOR SINGLE USE
SE DECISION MADE: 17-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACUSUPPLY, INC. ATTN: FERES DAGER 3801 NE 207TH STR. SUITE 501 AVENTURA, FL 33180	510(k) NO: K011248 PHONE NO : 305-932-9413	DEVICE: CW DISPOSABLE ACUPUNCTURE NEEDLE SE DECISION MADE: 29-OCT-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
ADAC LABORATORIES ATTN: DAVID KOLESAR 540 ALDER DR. MILPITAS, CA 95035	510(k) NO: K013496 PHONE NO : 408-468-3455	DEVICE: MODIFICATION TO SKYLIGHT IMAGING SYSTEM SE DECISION MADE: 06-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ADAC LABORATORIES ATTN: COLEEN A COLEMAN 540 ALDER DR. MILPITAS, CA 95035	510(k) NO: K013521 PHONE NO : 408-468-3051	DEVICE: GEMINI IMAGING SYSTEM SE DECISION MADE: 07-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ADJUNCTIVE THERAPEUTICS, INC. ATTN: MYRON Z BERNSTEIN 10 SCOTCH MIST COURT POTOMAC, MD 20854	510(k) NO: K002632 PHONE NO : 301-762-0802	DEVICE: OXYGENATOR SE DECISION MADE: 25-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
ADSIS LTD. ATTN: JONATHAN S KAHAN 555 THIRTEENTH STREET NW WASHINGTON, DC 20004-1109	510(k) NO: K010791 PHONE NO : 202-637-5794	DEVICE: REMOTE PRESENCE AND CARE SYSTEM (RPCS 5000) SE DECISION MADE: 08-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ADVANCE MEDICAL DESIGNS, INC. ATTN: BILL GILL 1241 ATLANTA INDUSTRIAL DR. MARIETTA, GA 30066	510(k) NO: K003670 PHONE NO : 770-422-3125	DEVICE: PATIENT DRAPE, SURGICAL SE DECISION MADE: 26-JAN-2001 510(k) STATEMENT
ADVANCE MEDICAL DESIGNS, INC. ATTN: BILL GILL 1241 ATLANTA INDUSTRIAL DR. MARIETTA, GA 30066	510(k) NO: K011265 PHONE NO : 770-422-3125	DEVICE: ULTRASOUND TRANSDUCER COVER SE DECISION MADE: 30-OCT-2001 510(k) STATEMENT
ADVANCE MEDICAL DESIGNS, INC. ATTN: BILL GILL 1241 ATLANTA INDUSTRIAL DR. MARIETTA, GA 30066	510(k) NO: K011422 PHONE NO : 770-422-3125	DEVICE: SURGICAL DRAPES SE DECISION MADE: 10-JUL-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 BIO-TECHNOLOGIES, INC.
ATTN: DAVID BRYANT
53 NEEDHAM DRIVE
SUITE 5, CW4 8FB
CRANAGE, CHESHIRE,

510(k) NO: K002488
PHONE NO : 011 441 477549392

DEVICE: KELO-COTE TOPICAL GEL
SE DECISION MADE: 05-JAN-2001

510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED DIAGNOSTICS, INC.
ATTN: STEVE HESLER
8112 304TH AVE. SE
PRESTON, WA 98050

510(k) NO: K013291
PHONE NO : 425-222-7169

DEVICE: ALTAIR MODEL, DEI SYSTEM (DIFFRACTIVE ENERGY IMAGING SYSTEM)
SE DECISION MADE: 14-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED MEDICAL SOLUTIONS LTD.
ATTN: CHRIS OAKES
ROAD THREE,
WINSFORD INDUSTRIAL ESTATE
WINSFORD, CHESHIRE,

510(k) NO: K010245
PHONE NO : 011 44 1606863500

DEVICE: ACTIVHEAL SCAR MANAGEMENT DRESSING
SE DECISION MADE: 25-APR-2001

510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED NEUROMODULATION SYSTEMS
ATTN: RASHMI MOZA
6501 WINDCREST DR.,
SUITE 100
PLANO, TX 75024

510(k) NO: K000852
PHONE NO : 972-309-8000

DEVICE: RENEW NEUROSTIMULATION SYSTEM
SE DECISION MADE: 19-JAN-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

ADVANCED RENAL TECHNOLOGIES, INC.
EMODIALYSIS
ATTN: ROBIN CALLAN
11838 N.E. 112TH ST.
KIRKLAND, WA 98033

510(k) NO: K010760
PHONE NO : 425-825-1276

DEVICE: ART BICARBONATE FOR HEMODIALYSIS, ART BICARBONATE LIQUID FOR H

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

ADVANCED RESPIRATORY
ATTN: ERIC J LARSON
1020 WEST COUNTY ROAD F
ST. PAUL, MN 55126

510(k) NO: K012928
PHONE NO : 651-234-1211

DEVICE: ABI VEST AIRWAY CLEARANCE SYSTEM
SE DECISION MADE: 09-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED SURGICAL CONCEPTS (ASC)
ATTN: MARY MCNAMARA-CULLINANE
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760

510(k) NO: K010711
PHONE NO : 508-643-0434

DEVICE: ECOTRACT ADJUSTABLE WOUND PROTECTOR/RETRACTOR
SE DECISION MADE: 22-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED SURGICAL CONCEPTS (ASC)
ATTN: MARY MCNAMARA-CULLINANE
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760

510(k) NO: K011183
PHONE NO : 508-643-0434

DEVICE: OMNIPORT HAND AND INSTRUMENT ACCESS DEVICE
SE DECISION MADE: 15-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED TECHNOLOGY LABORATORIES, 510(k) NO: K011224
), XRES IMAGING, AND PANORAMIC MEASUREMENT CAPABILITY
ATTN: TERRENCE J SWEENEY PHONE NO : 425-487-7602
22100 BOTHELL EVERETT HWY.
BOTHELL, WA 98041-3003

DEVICE: HDI 5000 ULTRASOUND SYSTEM WITH ASSISTED BORDER DETECTION (ABD
SE DECISION MADE: 04-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED UROSCIENCE, INC. 510(k) NO: K001807
ATTN: KAREN E PETERSON PHONE NO : 651-762-2146
1290 HAMMOND RD.
ST. PAUL, MN 55110

DEVICE: TISSUE MARKER
SE DECISION MADE: 03-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANTAGE DIAGNOSTICS CORP. 510(k) NO: K003708
ATTN: JANIS FREESTONE PHONE NO : 650-569-3852
1201 DOUGLAS AVE.
REDWOOD CITY, CA 94063

DEVICE: ADVANTAGE THC/COCAINE TEST
SE DECISION MADE: 22-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANTAGE DIAGNOSTICS CORP. 510(k) NO: K010921
ATTN: JANIS FREESTONE PHONE NO : 650-569-3852
1201 DOUGLAS AVE.
REDWOOD CITY, CA 94063

DEVICE: ADVANTAGE MARIJUANA (THC) HOME DRUG TEST
SE DECISION MADE: 25-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ADVANTAGE DIAGNOSTICS CORP. 510(k) NO: K011962
ATTN: JANIS FREESTONE PHONE NO : 44 146 067925
4 HOLYROOD STREET
CHARD, SOMERSET,

DEVICE: ADVANTAGE MARIJUANA (THC) AND COCAINE HOME DRUG TEST
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC. 510(k) NO: K002824
ATTN: DAVID W SCHLERF PHONE NO : 925-356-2640
200 GREGORY LANE
SUITE C-100
PLEASENT HILL, CA 94523-3389

DEVICE: MACS MODULAR ANTERIOR CONSTRUCT SYSTEM
SE DECISION MADE: 08-MAY-2001

510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC. 510(k) NO: K003463
ATTN: DAVID W SCHLERF PHONE NO : 925-356-2640
200 GREGORY LANE
SUITE C-100
PLEASENT HILL, CA 94523-3389

DEVICE: SOCON SPINAL SYSTEM
SE DECISION MADE: 11-APR-2001

510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC. 510(k) NO: K003519
ATTN: JOYCE THOMAS PHONE NO : 800-258-1946
944 MARCON BLVD
ALLENTOWN, PA 18109

DEVICE: YASARGIL PERMANENT ANEURYSM CLIPS
SE DECISION MADE: 29-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC. 510(k) NO: K003608
ATTN: LISA M MILLINGTON PHONE NO : 800-258-1946
944 MARCON BLVD
ALLENTOWN, PA 18109

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

AESCULAP, INC. ATTN: JOYCE THOMAS 3773 EXECUTIVE CENTER PARKWAY CENTER VALLEY, PA 18034	510(k) NO: K003612 PHONE NO : 800-258-1946	DEVICE: MICROSPEED EC MOTORSYSTEM GD650/GD653 SE DECISION MADE: 20-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. INSTRUMENTATION ATTN: DAVID W SCHLERF 200 GREGORY LANE SUITE C-100 PLEASENT HILL, CA 94523-3389	510(k) NO: K003740 PHONE NO : 925-356-2640	DEVICE: MIASPAS MINITTA ANTERIOR MICRO SURGICAL TRANSTHORACIC APPROACH SE DECISION MADE: 27-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: DAVID W SCHLERF 200 GREGORY LANE SUITE C-100 PLEASENT HILL, CA 94523-3389	510(k) NO: K003759 PHONE NO : 925-356-2640	DEVICE: AESCULAP SPIEGELBERG BRAIN PRESSURE MONITOR SE DECISION MADE: 28-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA M MILLINGTON 944 MAROON BLVD ALLENTOWN, PA 18109	510(k) NO: K003965 PHONE NO : 800-258-1946	DEVICE: MRI SAFE INSTRUMENTS SE DECISION MADE: 16-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LESLIE YOUNG 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K010752 PHONE NO : 800-258-1946	DEVICE: AESCULAP'S MODULAR ENDOSCOPIC INSTRUMENTS FOR GYNECOLOGY SE DECISION MADE: 11-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA M MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K011102 PHONE NO : 800-258-1946	DEVICE: ANTERIOR CRUCIATE LIGAMENT (ACL) INSTRUMENT SYSTEM SE DECISION MADE: 03-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. E ATTN: STEVE REITZLER 13221 MARICOTTE PLACE SAN DIEGO, CA 92130	510(k) NO: K011372 PHONE NO : 619-977-1465	DEVICE: AESCULAP, INC. SAFIL QUICK SYNTHETIC ABSORBABLE SURGICAL SUTUR SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: STEVE REITZLER 13221 MARICOTTE PLACE SAN DIEGO, CA 92130	510(k) NO: K011375 PHONE NO : 619-977-1465	DEVICE: AESCULAP, INC., MONOSYN SYNTHETIC ABSORBABLE SURGICAL SUTURE SE DECISION MADE: 29-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA M MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K011556 PHONE NO : 610-791-6882	DEVICE: MACS HMA ANTERIOR SPINAL STABILIZATION SYSTEM SE DECISION MADE: 16-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC. ATTN: STEVE REITZLER 13221 MARICOTTE PLACE SAN DIEGO, CA 92130	510(k) NO: K012201 PHONE NO : 619-977-1465	DEVICE: PREMICRON NONABSORBABLE PET SURGICAL SUTURE SE DECISION MADE: 19-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA M MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K012219 PHONE NO : 800-258-1946	DEVICE: SCALPFIX CLIP SYSTEM SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA M MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K012986 PHONE NO : 800-258-1946	DEVICE: BIPOLAR IRRIGATION FORCEPS SE DECISION MADE: 03-OCT-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
AFP IMAGING CORP. ATTN: MARY MCNAMARA-CULLINANE 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K013176 PHONE NO : 508-643-0434	DEVICE: MODIFICATION TO: SENS-A-RAY SYSTEM WITH PROIMAGE SOFTWARE SE DECISION MADE: 16-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
AFX, INC. D, MODEL SERIES 1000, P/N 102006, P/N 102007 ATTN: NANCY NORRIS 47929 FREMONT BOULEVARD FREMONT, CA 94538	510(k) NO: K003978 PHONE NO : 510-651-7430	DEVICE: AFX MICROWAVE GENERATOR, FLEX ABLATION WAND, LYNX ABLATION WAN SE DECISION MADE: 22-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
AGFA CORP. ATTN: T. WHIT ATHEY 12300 TWINBROOK PKWY,STE 625 ROCKVILLE, MD 20852	510(k) NO: K010571 PHONE NO : 301-770-9590	DEVICE: ADC QS/IPD WORKSTATION SE DECISION MADE: 28-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
AGFA CORP. ATTN: T.WHIT ATHEY 12300 TWINBROOK 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 CORP. ATTN: T. WHIT ATHEY 12300 TWINBROOK PKWY,STE 625 ROCKVILLE, MD 20852	510(k) NO: K012750 PHONE NO : 301-770-9590	DEVICE: ADC PEDIATRIC SE DECISION MADE: 14-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA

AGFA CORP. ATTN: T. WHIT ATHEY 12300 TWINBROOK PKWY,STE 625 ROCKVILLE, MD 20852	510(k) NO: K012941 PHONE NO : 301-770-9590	DEVICE: DRYSTAR, MODEL 4500M SE DECISION MADE: 29-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
AGFA MEDICAL IMAGING ATTN: KIRSTEN PAULSON 12300 TWINBROOK PKWY, STE 625 ROCKVILLE, MD 20852	510(k) NO: K010275 PHONE NO : 301-770-9590	DEVICE: DRYSTAR 4500 PRINTER, MODEL 4500 SE DECISION MADE: 27-APR-2001 510(k) STATEMENT
AGFA-GEVAERT AG ATTN: T. WHIT ATHEY 12300 TWINBROOK 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: K003763 PHONE NO : 805-604-0457	DEVICE: 2010 PLUS HOLTER FOR WINDOWS SE DECISION MADE: 05-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
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 HOLTER FOR WINDOWS SE DECISION MADE: 08-FEB-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
AGILENT TECHNOLOGIES DEUTSCHLAND G DULE, AGILENT INVASIVE PRESSURE MODULE, MODEL M1175A/76A ATTN: EGON PFEIL HERRENBERGER STRASSE 130 D 71034 BOEBLINGEN BOEBLINGEN,,	510(k) NO: K002758 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: TERESA SKARR 2401 FOURTH AVE., SUITE 500 SEATTLE, WA 98121	510(k) NO: K003819 PHONE NO : 206-664-5000	DEVICE: HEARTSTREAM ATTENUATED DEFIBRILLATION PADS, MODEL M3870A SE DECISION MADE: 02-MAY-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

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

510(k) NO: K010453
PHONE NO : 978-659-3173

DEVICE: M2376A DEVICELINK SYSTEM
SE DECISION MADE: 02-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES, INC.
EAM XLT DEFIBRILLATOR/MONITOR.MODEL M2500B
ATTN: RICHARD J PETERSEN
3000 MINUTEMAN RD.
ANDOVER, MA 01810-1099

510(k) NO: K010634
PHONE NO : 978-659-2213

DEVICE: HEARTSTREAM XL DEFIBIBRILLATOR/MONITOR, MODEL M4735A, HEARTSTR

SE DECISION MADE: 11-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES, INC.
M3154
ATTN: DAVE OSBORN
3000 MINUTEMAN RD.
ANDOVER, MA 01810-1099

510(k) NO: K011093
PHONE NO : 978-659-3178

DEVICE: AGILENT INFORMATION CENTER SOFTWARE FOR M3150,M3151,M3153 AND

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

AGILENT TECHNOLOGIES, INC.
ATTN: MIKE HUDON
3000 MINUTEMAN RD., MS 0491
ANDOVER, MA 01810-1099

510(k) NO: K011578
PHONE NO : 978-659-3173

DEVICE: M2376A DEVICELINK SYSTEM, MODEL M2376A
SE DECISION MADE: 08-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES, INC.
ATTN: DENISE HALEY
3000 MINUTEMAN RD.
ANDOVER, MA 01810-1099

510(k) NO: K011824
PHONE NO : 978-659-2701

DEVICE: AGILENT M2636B TELEMON B MONITOR (TELEMON B)
SE DECISION MADE: 02-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

AGILENT TECHNOLOGIES, INC.
ATTN: MIKE HUDON
3000 MINUTEMAN RD., MS 0491
ANDOVER, MA 01810-1099

510(k) NO: K012094
PHONE NO : 978-659-3173

DEVICE: MODIFICATION TO DEVICE LINK SYSTEM, MODEL M2376A
SE DECISION MADE: 20-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

AHAVA STEIN
DEVICE
ATTN: AHAVA STEIN
P.O.B. 454
GINOT SHOMRON, 44853,

510(k) NO: K000655
PHONE NO : 972 979 20673

DEVICE: PPCID- PNEUMATIC PERIPHERAL CIRCULATION IMPROVEMENT (FOOTREST)

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

AKTINA MEDICAL PHYSICS CORP.
R (ABC)
ATTN: JOAN ZACHAROPOULOS
360 NORTH ROUTE 9W
CONGERS, NY 10920

510(k) NO: K003330
PHONE NO : 845-268-0101

DEVICE: AKTINA MEDICAL PHYSICS CORPORATION ACTIVE BREATHING COORDINATC

SE DECISION MADE: 04-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALARIS MEDICAL SYSTEMS, INC.
ATTN: RENEE FLUET
10221 WATERIDGE CIRCLE
SAN DIEGO, CA 92121-2733
510(k) NO: K010965
PHONE NO : 858-458-7563
DEVICE: A-LINE AEP MONITOR
SE DECISION MADE: 27-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALARIS MEDICAL SYSTEMS, INC.
ATTN: RENEE L FLUET
10221 WATERIDGE CIRCLE
SAN DIEGO, CA 92121-2733
510(k) NO: K010966
PHONE NO : 858-458-7845
DEVICE: MEDLEY SP02 MODULE, MODEL 8220
SE DECISION MADE: 08-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALARIS MEDICAL SYSTEMS, INC.
(SE), MEDSYSTEM III INFUSION (MSIII), MEDSYSTEM PATIENT C
ATTN: RENEE L FLUET
10221 WATERIDGE CIRCLE
SAN DIEGO, CA 92121-2733
510(k) NO: K012383
PHONE NO : 858-458-7563
DEVICE: GEMINI PC-1,PC-2, PC-2TX,PC-4, SIGNATURE EDITION INFUSION PUMP
SE DECISION MADE: 02-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALARIS MEDICAL SYSTEMS, INC.
ATTN: RENEE L FLUET
10221 WATERIDGE CIR.
SAN DIEGO, CA 92121-2733
510(k) NO: K013087
PHONE NO : 858-458-7563
DEVICE: SINGLE DOSE DISPENSING PIN, MODEL 2201
SE DECISION MADE: 13-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALBERT BROWNE LTD.
ATTN: CYNTHIA J.M. NOLTE
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760
510(k) NO: K002937
PHONE NO : 508-643-0434
DEVICE: TST CONTROL INTEGRATOR FOR STEAM STERILIZERS
SE DECISION MADE: 05-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALBERT BROWNE LTD.
ND METRICIDE PLUS 30 SOLUTIONS
ATTN: CYNTHIA J.M. NOLTE
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760
510(k) NO: K012335
PHONE NO : 508-643-0434
DEVICE: BROWNE METREX 1.8% GLUTARALDEHYDE INDICATOR FOR METRICIDE 28 A
SE DECISION MADE: 01-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALCON RESEARCH, LTD.
ATTN: SHERRI J LAKOTA
6201 SOUTH FREEWAY
FORT WORTH, TX 76134-2099
510(k) NO: K003768
PHONE NO : 817-568-6179
DEVICE: MONARCH II IOL DELIVERY SYSTEM
SE DECISION MADE: 05-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALFA SCIENTIFIC DESIGNS, INC.
ATTN: NAISHU WANG
12330 STOWE DR.
POWAY, CA 92064
510(k) NO: K003647
PHONE NO : 858-513-3888
DEVICE: INSTANT-VIEW BARBITURATE URINE CASSETTE TEST
SE DECISION MADE: 29-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALFA SCIENTIFIC DESIGNS, INC.
TEST (DIP STRIP)
ATTN: NAISHU WANG
12330 STOWE DR.
POWAY, CA 92064
510(k) NO: K003845
PHONE NO : 858-513-3888
DEVICE: MODIFICATION TO INSTANT-VIEW METHAMPHETAMINE (METH 1000) URINE
SE DECISION MADE: 29-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K003847 PHONE NO : 858-513-3888	DEVICE: MODIFICATION TO INSTANT-VIEW METHAMPHETYAMINE (METH1000) URINE TEST (CASSETTE) SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAIISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K003879 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW BENZODIAZEPINE (BZD) URINE TEST (DIP STRIP) SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K003881 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW BENZODIAZEPINE (BZD) URINE CASSETTE TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K010014 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW METHADONE URINE DIP STRIP TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K010015 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW METHADONE URINE CASSETTE TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K010045 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW PHENCYCLIDINE (PCP) URINE DIP STRIP TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K010047 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW PHENCYCLIDINE (PCP) URINE CASSETTE TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K010079 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW MORPHINE (2000) URINE DIP STRIP TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALFA SCIENTIFIC DESIGNS, INC. ATTN: NAISHU WANG 12330 STOWE DR. POWAY, CA 92064	510(k) NO: K010080 PHONE NO : 858-513-3888	DEVICE: INSTANT-VIEW MORPHINE (2000) URINE CASSETTE TEST SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA

ALFA SCIENTIFIC DESIGNS, INC.
ATTN: NAISHU WANG
12330 STOWE DR.
POWAY, CA 92064
510(k) NO: K010125
PHONE NO : 619-350-9798
DEVICE: INSTANT-VIEW BARBITUATE URINE DIP STRIP TEST
SE DECISION MADE: 29-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
ATTN: ERICA SETHI
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

ALLEGIANCE HEALTHCARE CORP.
510(k) NO: K010862
DEVICE: ULTRAFREE MAX STERILE LATEX POWEDER-FREE SURGICAL GLOVES WITH PROTEIN LABELING CLAIM, 50 PER GRAM OR LESS OF TOTAL WATER
ATTN: ERICA SETHI
1500 WAUKEGAN RD. BLDG. WM
MCGAW PARK, IL 60085
PHONE NO : 847-785-3337
SE DECISION MADE: 07-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
ATTN: LANCE MARCONI
1500 WAUKEGAN RD.
MCGAW PARK, IL 60085
510(k) NO: K011078
PHONE NO : 847-785-3312
DEVICE: MALLEABLE SHAFT CLAMP
SE DECISION MADE: 13-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
ATTN: SHARON ROBBINS
1500 WAUKEGAN RD.
MCGAW PARK, IL 60085
510(k) NO: K011132
PHONE NO : 847-785-3311
DEVICE: AIRLIFE HEPA FILTER
SE DECISION MADE: 08-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
ATTN: ERICA SETHI
1500 WAUKEGAN RD.
MCGAW PARK, IL 60085
510(k) NO: K011186
PHONE NO : 847-785-3337
DEVICE: POWDER-FREE STERILE SYNTHETIC VINYL EXAMINATION GLOVES
SE DECISION MADE: 25-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
ATTN: ERICA SETHI
1500 WAUKEGAN RD.
MCGAW PARK, IL 60085
510(k) NO: K011721
PHONE NO : 847-785-3337
DEVICE: ESTEEM STERILE POLYISOPRENE SURGICAL GLOVES
SE DECISION MADE: 14-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ALLEGIANCE HEALTHCARE CORP.
510(k) NO: K012149
DEVICE: POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN, CHEMOTHERAP Y LABELING CLAIM
ATTN: ERICA SETHI
1500 WAUKEGAN RD. BLDG. WM
MCGAW PARK, IL 60085
PHONE NO : 847-785-3337
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

ALLEGIANCE HEALTHCARE CORP. 510(k) NO: K013302 DEVICE: DURAPRENE STERILE SYNTHETIC POWDER-FREE SURGICAL GLOVES WITH T
ESTED FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM
ATTN: ERICA SETHI PHONE NO : 847-785-3337 SE DECISION MADE: 17-DEC-2001
1500 WAUKEGAN RD. BLDG. WM 510(k) SUMMARY AVAILABLE FROM FDA
MCGAW PARK, IL 60085

ALLERGAN, INC. 510(k) NO: K003252 DEVICE: COMPLETE BRAND MULTI-PURPOSE SOLUTION
ATTN: PAUL J NOWACKI PHONE NO : 714-246-6761 SE DECISION MADE: 21-FEB-2001
2525 DUPONT DR.
P.O. BOX 19534 510(k) SUMMARY AVAILABLE FROM FDA
IRVINE, CA 92612

ALLERGAN, INC. 510(k) NO: K003638 DEVICE: MOJAVE CATARACT EXTRACTION SYSTEM
ATTN: MARK O'DONNELL PHONE NO : 714-246-2226 SE DECISION MADE: 13-FEB-2001
2525 DUPONT DR.
P.O. BOX 19534 510(k) SUMMARY AVAILABLE FROM FDA
IRVINE, CA 92612

ALLIANCE MEDICAL CORP. 510(k) NO: K011192 DEVICE: COMPRESSIBLE LIMB SLEEVE
ATTN: DON SELVEY PHONE NO : 480-763-5300 SE DECISION MADE: 26-NOV-2001
10232 SOUTH 51ST STREET 510(k) SUMMARY AVAILABLE FROM FDA
PHOENIX, AZ 85044

ALLIANCE MEDICAL CORP. 510(k) NO: K012603 DEVICE: REPROCESSED AUTOSUTURE UNIPOLAR LAPAROSCOPIC/ENDOSCOPIC INSTRU
MENTS
ATTN: DON SELVEY PHONE NO : 480-763-5300 SE DECISION MADE: 07-NOV-2001
10232 SOUTH 51ST. STREET 510(k) SUMMARY AVAILABLE FROM FDA
PHOENIX, AZ 85044

ALLIANCE MEDICAL CORP. 510(k) NO: K012605 DEVICE: REPROCESSED ATHROSCOPICS BURS
ATTN: DON SELVEY PHONE NO : 480-763-5300 SE DECISION MADE: 07-NOV-2001
10232 SOUTH 51ST. STREET 510(k) SUMMARY AVAILABLE FROM FDA
PHOENIX, AZ 85044

ALLIANCE MEDICAL CORP. 510(k) NO: K012625 DEVICE: REPROCESSED UNIPOLAR LAPAROSCOPIC/ENDOSCOPIC INSTRUMENTS
ATTN: DON SELVEY PHONE NO : 480-763-5300 SE DECISION MADE: 22-OCT-2001
10232 SOUTH 51ST ST. 510(k) SUMMARY AVAILABLE FROM FDA
PHOENIX, AZ 85044

ALLIANCE MEDICAL CORP. 510(k) NO: K012631 DEVICE: REPROCESSED SOFT TISSUE ABLATORS
ATTN: DON SELVEY PHONE NO : 480-763-5300 SE DECISION MADE: 06-DEC-2001
10232 SOUTH 51ST ST. 510(k) SUMMARY AVAILABLE FROM FDA
PHOENIX, AZ 85044

ALLIANCE MEDICAL CORP. 510(k) NO: K012635 DEVICE: REPROCESSED STRYKER ARTHROSCOPIC SHAVERS
ATTN: DON SELVEY PHONE NO : 480-763-5300 SE DECISION MADE: 07-NOV-2001
10232 SOUTH 51ST ST. 510(k) SUMMARY AVAILABLE FROM FDA
PHOENIX, AZ 85044

ALLIANCE MEDICAL CORP. ATTN: DON SELVEY 10232 SOUTH 51ST ST. PHOENIX, AZ 85044	510(k) NO: K012638 PHONE NO : 480-763-5300	DEVICE: REPROCESSED LAPAROSCOPIC/ENDOSCOPIC INSTRUMENTS SE DECISION MADE: 08-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALLIANCE MEDICAL CORP. ATTN: DON SELVEY 10232 SOUTH 51ST. STREET PHOENIX, AZ 85044	510(k) NO: K012652 PHONE NO : 480-763-5300	DEVICE: REPROCESSED DYONICS ARTHROSCOPIC BURS SE DECISION MADE: 08-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALLIANCE MEDICAL, INC. ATTN: DON SELVEY 10232 SOUTH 51 STREET PHOENIX, AZ 85044	510(k) NO: K012611 PHONE NO : 480-763-5300	DEVICE: REPROCESSED DYONICS ARTHROSCOPIC SHAVERS SE DECISION MADE: 07-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALLIANCE MEDICAL, INC. ATTN: DON SELVEY 10232 SOUTH 51 STREET PHOENIX, AZ 85044	510(k) NO: K012613 PHONE NO : 480-763-5300	DEVICE: REPROCSSED LINVATEC SHAVERS SE DECISION MADE: 07-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALLIANCE MEDICAL, INC. ATTN: DON SELVEY 10232 SOUTH 51 STREET PHOENIX, AZ 85044	510(k) NO: K012630 PHONE NO : 480-763-5300	DEVICE: REPROCESSED LINVATEC ARTHROSCOPIC BURS SE DECISION MADE: 09-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALLIANCE MEDICAL, INC. ATTN: DON SELVEY 10232 SOUTH 51 STREET PHOENIX, AZ 85044	510(k) NO: K012637 PHONE NO : 480-763-5300	DEVICE: REPROCESSED PHACOEMULSIFICATION TIPS SE DECISION MADE: 07-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALOKA CO., LTD. ULTRASOUND SYSTEM ATTN: KELVIN BURROUGHS 10 FAIRFIELD BLVD. WALLINGFORD, CT 06492	510(k) NO: K011314 PHONE NO : 203-269-5088	DEVICE: OLYMPUS GF UC140P-AL5 ULTRASONIC ENDOSCOPE WITH ALOKA SSD-5500 SE DECISION MADE: 15-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALOKA CO., LTD. ATTN: KELVIN BURROUGHS 10 FAIRFIELD BLVD. WALLINGFORD, CT 06492	510(k) NO: K011315 PHONE NO : 203-269-5088	DEVICE: SSD 5500 WITH OLYMPUS GF TYPE UC140P-AL5 SE DECISION MADE: 15-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALOKA CO., LTD. ATTN: KELVIN BURROUGHS 10 FAIRFIELD BLVD. WALLINGFORD, CT 06492	510(k) NO: K011457 PHONE NO : 203-269-5088	DEVICE: ALOKA SSD-5500 WITH KI AND A-SMA SE DECISION MADE: 23-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA

ALOKA CO., LTD. ATTN: KELVIN BURROUGHS 10 FAIRFIELD BLVD. WALLINGFORD, CT 06492	510(k) NO: K012080 PHONE NO : 203-269-5088	DEVICE: SSD-5000 DIAGNOSTIC ULTRASOUND SYSTEM SE DECISION MADE: 29-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALOKA CO., LTD. ATTN: KELVIN BURROUGHS 10 FAIRFIELD BLVD. WALLINGFORD, CT 06492	510(k) NO: K012253 PHONE NO : 203-269-5088	DEVICE: SSD-1000 DIAGNOSTIC ULTRASOUND SYSTEM SE DECISION MADE: 30-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALPHA VISTA, INC. ATTN: HELMUT WEBER 42 DIGITAL DR., SUITE 12 NOVATA, CA 94949	510(k) NO: K003031 PHONE NO : 415-382-9146	DEVICE: LENSOCLEAN MULTI-PURPOSE SOLUTION, MODEL 355ML SE DECISION MADE: 05-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ALTUS MEDICAL II ATTN: MICHAEL LEVERNIER 821 COWAN RD. BURLINGAME, CA 94010	510(k) NO: K003202 PHONE NO : 650-552-9700	DEVICE: FAMILY OF ALTUS MEDICAL COOLGLIDE AESTHETIC LASERS, MODELS I & SE DECISION MADE: 10-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
AMBU, INC. ATTN: SANJAY PARIKH 611 NORTH HAMMONDS FERRY RD. LINTHICUM, MD 21090-1356	510(k) NO: K010583 PHONE NO : 410-636-1144	DEVICE: AMBU GEL, HYDROGEL BURN DRESSING SE DECISION MADE: 25-MAY-2001 510(k) STATEMENT
AMEDITECH, INC. ATTN: JOHN WU 10340 CAMINO SANTA FE, STE F SAN DIEGO, CA 92121	510(k) NO: K011813 PHONE NO : 858-535-1968	DEVICE: AMEDITECH IMMUTEST DRUG SCREEN THC SE DECISION MADE: 22-OCT-2001 510(k) STATEMENT
AMEDITECH, INC. ATTN: JOHN WU 10340 CAMINO SANTA FE, STE F SAN DIEGO, CA 92121	510(k) NO: K011814 PHONE NO : 858-535-1968	DEVICE: AMEDITECH IMMUTEST DRUG SCREEN COC SE DECISION MADE: 22-OCT-2001 510(k) STATEMENT
AMEDITECH, INC. ATTN: JOHN WU 10340 CAMINO SANTA FE, STE F SAN DIEGO, CA 92121	510(k) NO: K012483 PHONE NO : 858-535-1968	DEVICE: AMEDITECH IMMUTEST DRUG SCREEN OPIATES SE DECISION MADE: 30-NOV-2001 510(k) STATEMENT
AMEDITECH, INC. ATTN: JOHN WU 10340 CAMINO SANTA FE, STE F SAN DIEGO, CA 92121	510(k) NO: K012484 PHONE NO : 858-535-1968	DEVICE: AMEDITECH IMMUTEST DRUG SCREEN AMPHETAMINE SE DECISION MADE: 30-NOV-2001 510(k) STATEMENT

AMEDITECH, INC.
ATTN: JOHN WU
10340 CAMINO SANTA FE, STE F
SAN DIEGO, CA 92121

510(k) NO: K012582
PHONE NO : 858-535-1968

DEVICE: AMEDITECH IMMUTEST DRUG SCREEN PCP
SE DECISION MADE: 30-NOV-2001
510(k) STATEMENT

AMEDITECH, INC.
ATTN: JOHN WU
10340 CAMINO SANTA FE, STE F
SAN DIEGO, CA 92121

510(k) NO: K012585
PHONE NO : 858-535-1968

DEVICE: AMEDITECH IMMUTEST DRUG SCREEN METHAMPHETAMINE
SE DECISION MADE: 16-NOV-2001
510(k) STATEMENT

AMERICAN BIO MEDICA CORP.
ATTN: FRAN WHITE
163 CABOT STREET
BEVERLY, MA 01915

510(k) NO: K012159
PHONE NO : 978-927-3808

DEVICE: RAPID DRUG SCREEN
SE DECISION MADE: 25-JUL-2001
510(k) STATEMENT

AMERICAN BIO MEDICA CORP.
ATTN: HENRY WELLS
9110 RED BRANCH ROAD
COLUMBIA, MD 21945

510(k) NO: K012164
PHONE NO : 410-992-4734

DEVICE: 'RAPIDONE'-METHADONE TEST
SE DECISION MADE: 20-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN BIO MEDICA CORP.
ATTN: HENRY WELLS
9110 RED BRANCH ROAD
COLUMBIA, MD 21045

510(k) NO: K013180
PHONE NO : 410-992-4734

DEVICE: RAPIDONE-ECSTASY TEST
SE DECISION MADE: 26-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN BIOCURVE, INC.
LENS FOR DAILY WEAR (CLEAR & BLUE VISIBILITY TINT, LATHE
ATTN: MARTIN DALSING
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

AMERICAN BIOCURVE, INC.
LENS FOR DAILY WEAR (CLEAR AND BLUE VISIBILITY-HANDLING L
ATTN: MARTIN DALSING
623 GLACIER DR.
GRAND JUNCTION, CO 81503

510(k) NO: K011234
PHONE NO : 970-243-5490

DEVICE: BIOCURVE SOFT (HIOXIFILCON B) SPHERICAL AND TORIC SOFT CONTACT

SE DECISION MADE: 13-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN CONTACT LENS, INC.
LENS FOR DAILY WEAR (CLEAR, LATHE-CUT)
ATTN: MARTIN DALSING
623 GLACIER DRIVE
GRAND JUNCTION, CO 81503

510(k) NO: K010223
PHONE NO : 970-243-5490

DEVICE: BIOCURVE SOFT (METHAFILCON A) SPHERICAL AND TORIC SOFT CONTACT

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

AMERICAN CONTACT LENS, INC.
LENS FOR DAILY WEAR (CLEAR AND BLUE VISIBILITY-HANDLING T
ATTN: MARTIN DALSING
623 GLACIER DRIVE
GRAND JUNCTION, CO 81503

510(k) NO: K011316
PHONE NO : 970-243-5490

DEVICE: BIOCURVE SOFT (HIOXIFILCOM A) SPHERICAL AND TORIC SOFT CONTACT

SE DECISION MADE: 13-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN DENT-ALL, INC. ATTN: VACHAKAN H KHOIE 5140 SAN FERNANDO ROAD GLENDALE, CA 91204	510(k) NO: K003509 PHONE NO : 818-662-0618	DEVICE: FLEXICAST SE DECISION MADE: 02-JAN-2001 510(k) STATEMENT
AMERICAN DENT-ALL, INC. ATTN: VACHAKAN H KHOIE 5140 SAN FERNANDO ROAD GLENDALE, CA 91204	510(k) NO: K011705 PHONE NO : 818-662-0618	DEVICE: SUPREMCAST SE DECISION MADE: 03-AUG-2001 510(k) STATEMENT
AMERICAN DENT-ALL, INC. ATTN: VACHAKAN H KHOIE 5140 SAN FERNANDO ROAD GLENDALE, CA 91204	510(k) NO: K011706 PHONE NO : 818-662-0618	DEVICE: FLEXICAST PRIME SE DECISION MADE: 06-AUG-2001 510(k) STATEMENT
AMERICAN DENTAL TECHNOLOGIES, INC. ATTN: SHEILA HEMEON-HEYER 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K012127 PHONE NO : 508-643-0434	DEVICE: PULSEMASTER ERBIUM DENTAL LASER SYSTEM SE DECISION MADE: 04-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN DENTAL TECHNOLOGIES, INC. ATTN: JOHN VICKERS 5555 BEAR LANE CORPUS CHRISTI, TX 78405	510(k) NO: K012213 PHONE NO : 361-289-1145	DEVICE: GULLIVER AND CLASSE A SE DECISION MADE: 13-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN DIAGNOSTIC CORP. ATTN: MARC BLITSTEIN 55 COMMERCE DR. HAUPPAUGE, NY 11788	510(k) NO: K012304 PHONE NO : 516-273-9600	DEVICE: ADC 656 ELECTRONIC STETHOSCOPE SE DECISION MADE: 01-NOV-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 LABORATORY PRODUCTS CO., ATTN: RICHARD E CONLEY P.O. BOX 451 WINDHAM, NH 03087	510(k) NO: K011201 PHONE NO : 603-893-8914	DEVICE: ALPCO MILENIA ANTI-TPO ELISA SE DECISION MADE: 24-MAY-2001 510(k) STATEMENT
AMERICAN LABORATORY PRODUCTS CO., ATTN: RICHARD E CONLEY P.O. BOX 451 WINDHAM, NH 03087	510(k) NO: K011415 PHONE NO : 603-893-8914	DEVICE: ALPCO MILENIA ANTI-TG EIA SE DECISION MADE: 30-MAY-2001 510(k) STATEMENT
AMERICAN LASER CORP. ATTN: DANIEL HOEFER 2417 SOUTH 3850 WEST SALT LAKE CITY, UT 84120	510(k) NO: K010046 PHONE NO : 801-972-1311	DEVICE: NUVOLASE 532 MEDICAL LASER SYSTEM SE DECISION MADE: 05-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: ELSA LINKE
10700 BREN RD., WEST
MINNETONKA, MN 55343
510(k) NO: K010277
PHONE NO : 800-328-3881
DEVICE: AMS FASCIAL-ANCHORING SYSTEM
SE DECISION MADE: 26-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: ELSA A LINKE
10700 BREN RD., WEST
MINNETONKA, MN 55343
510(k) NO: K010931
PHONE NO : 952-930-6309
DEVICE: AMS SACRAL COLPOPEXY SLING, MODEL 72403501
SE DECISION MADE: 09-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: ELSA A LINKE
10700 BREN RD., WEST
MINNETONKA, MN 55343
510(k) NO: K010990
PHONE NO : 952-930-6309
DEVICE: AMS SLING FIXATION SYSTEM
SE DECISION MADE: 22-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: GINGER S GLASER
10700 BREN RD., WEST
MINNETONKA, MN 55343
510(k) NO: K011251
PHONE NO : 952-930-6541
DEVICE: SPARC SLING SYSTEM
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: ELSA A LINKE
10700 BREN RD., WEST
MINNETONKA, MN 55343
510(k) NO: K011910
PHONE NO : 952-930-6309
DEVICE: IN-FAST BONE SCREW SYSTEM
SE DECISION MADE: 13-JUL-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

AMERICAN MEDICAL SYSTEMS, INC.
ATTN: GINGER S GLASER
10700 BREN RD., WEST
MINNETONKA, MN 55343
510(k) NO: K013355
PHONE NO : 952-930-6541
DEVICE: SPARC SLING SYSTEM
SE DECISION MADE: 26-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN TELECARE, INC.
X 1010
ATTN: CHARLES RICHARD ABBRUSCATO
7640 GOLDEN TRIANGLE DR.
EDEN PRAIRIE, MN 55344-3732
510(k) NO: K003999
PHONE NO : 952-897-0000
DEVICE: AVIVA SYSTEM, MODEL SL 2020; AVIVA SLX SYSTEM SYSTEM, MODEL SL
SE DECISION MADE: 28-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMERITEK MEDICAL, INC.
ATTN: GREG WIITA
2655 NORTH OCEAN DRIVE
SINGER ISLAND, FL 33404
510(k) NO: K011581
PHONE NO : 561-842-7595
DEVICE: AMERITEK BRACHYTHERAPY TEMPLATE
SE DECISION MADE: 17-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

AMIGO MOBILITY INTL., INC. ATTN: MIKE LABRAKE 6693 DIXIE HWY. BRIDGEPORT, MI 48722	510(k) NO: K010503 PHONE NO : 517-777-0910	DEVICE: AMIGO WHEELCHAIR SE DECISION MADE: 06-JUL-2001 510(k) STATEMENT
AMIRA MEDICAL, INC. ATTN: NINA PELED 4742 SCOTTS VALLEY DR. SCOTTS VALLEY, CA 95066	510(k) NO: K010605 PHONE NO : 408-440-5448	DEVICE: ATLAST DATA MANAGEMENT SOFTWARE (DMS) SE DECISION MADE: 07-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
AMYSYSTEMS ATTN: SYLVAIN DUGAS 178, WEST SERVICE ROAD CHAMPLAIN, NY 12919	510(k) NO: K011006 PHONE NO : 514-453-0311	DEVICE: AMYSEAT TILT/RECLINE SEATING SE DECISION MADE: 11-MAY-2001 510(k) STATEMENT
ANALOGIC CORP. ATTN: STEVEN A CLARKE 360 AUDUBON RD. WAKEFIELD, MA 01880	510(k) NO: K011304 PHONE NO : 978-977-3000	DEVICE: OB-1 FETAL MONITOR SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ANALYTICAL INDUSTRIES, INC. ATTN: PATRICK J PRINDIBLE 2855 METROPOLITAN PLACE POMONA, CA 91767	510(k) NO: K002382 PHONE NO : 909-392-6900	DEVICE: 'ALL 2000' % OXYGEN ANALYZER SE DECISION MADE: 14-MAR-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
ANCHOR MEDICAL TECHNOLOGIES ATTN: GREG HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K010884 PHONE NO : 949-262-0411	DEVICE: TITANIUM COMPRESSION ANCHOR SYSTEM SE DECISION MADE: 20-JUN-2001 510(k) STATEMENT
ANDERSEN PRODUCTS, INC. ATTN: WENDY HEDRICK 3202 CAROLINE DR., HEALTH SCIENCE PARK HAW RIVER, NC 27258-8710	510(k) NO: K011077 PHONE NO : 336-376-3000	DEVICE: ANDERSEN INTESTINAL TUBE, MILLER-ABBOTT TYPE (AN 22) SE DECISION MADE: 09-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ANDREAS PEIN MEDIZINTECHNIK GMBH ATTN: ROBERT N CLARK 13605 WEST 7TH AVENUE GOLDEN, CO 80401-4604	510(k) NO: K012464 PHONE NO : 303-234-9412	DEVICE: HELIX HYDRO-JET SE DECISION MADE: 10-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA

ANDROMED, INC.
ATTN: JULIA LALE AKTIK
4610 BOIS-FRANC ROAD
SAINT-LAURENT, QUEBEC,
510(k) NO: K010729
PHONE NO : 514 336 0043
DEVICE: AGILENT ELECTRONIC STETHOSCOPE, MODELS M4532A AND M4533A
SE DECISION MADE: 26-OCT-2001
510(k) STATEMENT

ANGIODYNAMICS, INC.
ATTN: TERI JUCKETT
603 QUEENSBURY AVE.
QUEENSBURY, NY 12804
510(k) NO: K003901
PHONE NO : 518-798-1215
DEVICE: ANGIODYNAMICS SOFT-VU SIZING ANGIOGRAPHIC CATHETER
SE DECISION MADE: 17-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANIMAS CORP.
ATTN: MICHAEL J ANDREWS
590 E. LANCASTER AVENUE
FRAZER, PA 19355
510(k) NO: K012754
PHONE NO : 610-644-8990
DEVICE: EZ SET INFUSION SET
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANSELL HEALTHCARE PRODUCTS, INC.
TEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)
ATTN: JAMES R CHATTERTON
1875 HARSH AVENUE, SE
MASSILLON, OH 44646
510(k) NO: K003771
PHONE NO : 330-833-2811
DEVICE: ENCORE POWDER-FREE LATEX SURGICAL GLOVES, ORTHOPAEDIC WITH PRC
SE DECISION MADE: 16-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANSELL HEALTHCARE PRODUCTS, INC.
ITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)
ATTN: JAMES R CHATTERTON
1875 HARSH AVENUE, SE
MASSILLON, OH 44646
510(k) NO: K010961
PHONE NO : 330-833-2811
DEVICE: X-TENDA CUFF POWDER FREE NON-STERILE LATEX EXAMINATION GLOVE W
SE DECISION MADE: 31-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANSELL HEALTHCARE PRODUCTS, INC.
GLOVES, COLOR BLUE NON-STERILE
ATTN: JAMES R CHATTERTON
1875 HARSH AVENUE, SE
MASSILLON, OH 44646
510(k) NO: K011593
PHONE NO : 330-833-2811
DEVICE: MICRO-TOUCH NITRILE POWDER FREE SYNTHETIC MEDICAL EXAMINATION
SE DECISION MADE: 21-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANSELL HEALTHCARE PRODUCTS, INC.
VES , MODEL STYLE 65
ATTN: JAMES R CHATTERTON
1875 HARSH AVENUE, SE
MASSILLON, OH 44646
510(k) NO: K013603
PHONE NO : 330-833-2811
DEVICE: MODIFICATION TO:MICRO TOUCH (R) POWDER FREE LATEX SURGICAL GLC
SE DECISION MADE: 13-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANSELL HEALTHCARE PRODUCTS, INC.
S
ATTN: JAMES R CHATTERTON
1875 HARSH AVENUE, SE
MASSILLON, OH 44646
510(k) NO: K013604
PHONE NO : 330-833-2811
DEVICE: MODIFICATION TO: ULTRALON (R) POWDER FREE LATEX SURGICAL GLOVE
SE DECISION MADE: 13-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANSELL PERRY
NTENT LABELING CLAIM 50 MICROGRAMS OR LESS, MODEL STYLE 21
ATTN: JAMES R CHATTERTON
1875 HARSH AVENUE, S.E.
MASSILLON, OH 44646-7199
510(k) NO: K003895
PHONE NO : 330-833-2811
DEVICE: X-TENDA CUFF POWDER FREE LATEX SURGICAL GLOVES WITH PROTEIN CC
SE DECISION MADE: 17-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ANTYLLOS MEDIZINTECHNIK GMBH ATTN: HARALD JUNG UNTERER WINKEL 3 WURMLINGEN,	510(k) NO: K010192 PHONE NO : 004 974 61969236	DEVICE: ENDOSCOPIC TUBE SHAFT INSTRUMENTS FOR MONOPLAR COAGULATION SE DECISION MADE: 02-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX BIOTECHNOLOGY CORP. ATTN: STEVEN CREES 3600 HOLLY LANE N. SUITE 90 PLYMOUTH, MN 55447	510(k) NO: K002621 PHONE NO : 763-519-1664	DEVICE: GLUCOSURE BLOOD GLUCOSE MONITORING SYSTEM SE DECISION MADE: 22-JAN-2001 510(k) STATEMENT
APEX BIOTECHNOLOGY CORP. ATTN: STEVEN CREES 3600 HOLLY LANE N. SUITE 90 PLYMOUTH, MN 55447	510(k) NO: K002624 PHONE NO : 763-519-1664	DEVICE: GLUCOSMART BLOOD GLUCOSE MONITORING SYSTEM SE DECISION MADE: 22-JAN-2001 510(k) STATEMENT
APEX BIOTECHNOLOGY CORP. ATTN: BRUCE A MACFARLANE 5182 WEST 76TH STREET MINNEAPOLIS, MN 55439	510(k) NO: K011233 PHONE NO : 952-646-3188	DEVICE: MODIFICATION TO GLUCOSURE BGM SYSTEM, MODEL 221100 SE DECISION MADE: 18-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX DENTAL MATERIALS, INC. ATTN: SCOTT LAMERAND 603 BERKLEY COURT SCHUMBURG, IL 60194	510(k) NO: K010544 PHONE NO : 847-490-1014	DEVICE: VERTEX L/C ORTHODONTIC DIRECT BONDING PASTE SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX DENTAL MATERIALS, INC. ATTN: SCOTT LAMERAND 603 BERKLEY COURT SCHUMBURG, IL 60194	510(k) NO: K010547 PHONE NO : 847-490-1014	DEVICE: VERTEX SEALAND L/C ORTHODONTIC SEALANT SE DECISION MADE: 16-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX DENTAL MATERIALS, INC. ATTN: SCOTT LAMERAND 603 BERKLEY COURT SCHUMBURG, IL 60194	510(k) NO: K010849 PHONE NO : 847-490-1014	DEVICE: VERTEX ETCHANT SE DECISION MADE: 14-SEP-2001 510(k) STATEMENT
APEX MEDICAL CORP. -V), MODEL AP-102050T ATTN: DANIEL LEE 10TH FL., NO. 31, LANE 169, KANG NING ST. HSI CHIH CHEN, TAIPEI HSIEN,	510(k) NO: K002336 PHONE NO : 886 226 954122	DEVICE: MS104A, NEWMINI II (EMS-II), MODEL AP-101050T AND MEDTRIM (EMS SE DECISION MADE: 27-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX MEDICAL CORP. MODEL TS-140600 ATTN: DANIEL LEE 10TH FL., NO. 31, LANE 169, KANG NING ST. HSI CHIH CHEN, TAIPEI HSIEN,	510(k) NO: K002339 PHONE NO : 886 226 954122	DEVICE: AEMS V, EMS-1000, MODEL TS-140500 AND AEMS VI, EMS-1000 PLUS, SE DECISION MADE: 24-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

APEX MEDICAL CORP. ATTN: ALAN CHANG 10TH FL., NO. 31, LANE 169, KANG NING ST. HSI CHIH CHEN, TAIPEI HSIEN,	510(k) NO: K012140 PHONE NO : 886 226 954170	DEVICE: COM-PATCH SE DECISION MADE: 05-OCT-2001 510(k) STATEMENT
APEX MEDICAL CORP. ATTN: ALAN CHANG 10TH FL., NO. 31, LANE 169, KANG NING ST. HSI CHIH CHEN, TAIPEI HSIEN,	510(k) NO: K012643 PHONE NO : 886 226 954170	DEVICE: APEX MEDICAL LCD TENS-VII SE DECISION MADE: 29-OCT-2001 510(k) STATEMENT
APEX MEDICAL CORP. ATTN: ALAN CHANGE 10TH FL., NO. 31, LANE 169, KANG NING ST. HSI CHIH CHEN, TAIPEI HSIEN,	510(k) NO: K013813 PHONE NO : 886 226 954170	DEVICE: MODIFICATION TO:APEX MEDICAL IF-4100 SE DECISION MADE: 14-DEC-2001 510(k) STATEMENT
APEX SURGICAL, LLC. ATTN: EDWARD J CHEAL 12 HARDING STREET,SUITE 202 LAKEVILLE, MA 02347	510(k) NO: K003923 PHONE NO : 508-947-6500	DEVICE: APEX MODULAR ZIRCONIA FEMORAL HEAD SE DECISION MADE: 20-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
APEX SURGICAL, LLC. ATTN: EDWARD J CHEAL 12 HARDING STREET,SUITE 202 LAKEVILLE, MA 02347	510(k) NO: K012918 PHONE NO : 508-947-6500	DEVICE: APEX MODULAR ALUMINA FEMORAL HEAD SE DECISION MADE: 27-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
APOGEE MEDICAL, INC. ATTN: BRENT D ROBLING 90 WEATHERS ST. YOUNGSVILLE, NC 27549	510(k) NO: K011552 PHONE NO : 919-570-9605	DEVICE: UROLOGICAL CATHETER SE DECISION MADE: 18-JUL-2001 510(k) STATEMENT
APOLLO CORP. ATTN: ADRIAN SWEEN 450 MAIN ST. SOMERSET, WI 54025	510(k) NO: K012029 PHONE NO : 715-247-5625	DEVICE: REMEDY MODEL 2Z12 SE DECISION MADE: 31-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
APOTHECUS PHARMACEUTICAL CORP. ATTN: GARY L YINGLING 1900 K STREET, N.W. WASHINGTON, DC 20006-1108	510(k) NO: K010182 PHONE NO : 202-496-7645	DEVICE: VCF PERSONAL LUBRICANT SE DECISION MADE: 09-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
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 BIOTECH, INC. ATTN: DAVE D SMITH 10237 FLANDERS CT. SAN DIEGO, CA 92121	510(k) NO: K003466 PHONE NO : 858-587-6771	DEVICE: APPLIED BIOTECH, INC. SURESTEP AMP II DRUG SCREEN TEST SE DECISION MADE: 27-MAR-2001 510(k) STATEMENT
APPLIED BIOTECH, INC. ATTN: DAVE D SMITH 10237 FLANDERS CT. SAN DIEGO, CA 92121	510(k) NO: K010556 PHONE NO : 858-713-9614	DEVICE: SURESTEP FSH MENOPAUSE TEST SE DECISION MADE: 09-JUL-2001 510(k) STATEMENT
APPLIED BIOTECH, INC. ATTN: DAVE D SMITH 10237 FLANDERS CT. SAN DIEGO, CA 92121	510(k) NO: K010614 PHONE NO : 858-713-9614	DEVICE: SURESTEP ACETAMINOPHEN/SALICYLATE TEST SE DECISION MADE: 30-APR-2001 510(k) STATEMENT
APPLIED BIOTECH, INC. ATTN: DAVE D SMITH 10237 FLANDERS CT. SAN DIEGO, CA 92121	510(k) NO: K011133 PHONE NO : 858-713-9614	DEVICE: SURESTEP MDMA (ECSTASY) DRUG SCREEN TEST SE DECISION MADE: 20-JUN-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 DIABETES RESEARCH, INCORPO ATTN: CHARLES H KYPER 103 NOLEN LANE CHAPEL HILL, NC 27516	510(k) NO: K012429 PHONE NO :	DEVICE: SURESET INFUSION SET, MODEL 8023 SE DECISION MADE: 06-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
APPLIED MEDICAL ATTN: ANIL BHALANI 22872 AVENIDA EMPRESA RANCHO SANTA MARGARITA, CA 92688	510(k) NO: K002915 PHONE NO : 949-713-8327	DEVICE: FLEXIBLE OCCLUSION SYSTEM SE DECISION MADE: 08-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
APPLIED MEDICAL RESOURCES CORP. ATTN: ANIL BHALANI 22872 AVENIDA EMPRESSA RANCHO SANTA MARGARITA, CA 92688	510(k) NO: K003871 PHONE NO : 949-713-8327	DEVICE: LAPAROSCOPIC HAND PORT SE DECISION MADE: 31-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
APPLIED MEDICAL RESOURCES CORP. ATTN: ANIL BHALANI 22872 AVENIDA EMPRESSA RANCHO SANTA MARGARITA, CA 92688	510(k) NO: K010006 PHONE NO : 949-713-8327	DEVICE: DRAINAGE CATHETER OR FOLEY CATHETER SE DECISION MADE: 25-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA

APPLIED MEDICAL RESOURCES CORP.
ATTN: ANIL BHALANI
22872 AVENIDA EMPRESSA
RANCHO SANTA MARGARITA, CA 92688
510(k) NO: K011236
PHONE NO : 949-713-8000
DEVICE: MODIFICATION TO IMPLANTABLE CLIP
SE DECISION MADE: 14-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

APPLIED MEDICAL RESOURCES CORP.
ATTN: ANIL BHALANI
22872 AVENIDA EMPRESSA
RANCHO SANTA MARGARITA, CA 92688
510(k) NO: K011264
PHONE NO : 949-713-8327
DEVICE: MESH URETERAL STENT
SE DECISION MADE: 17-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

APPLIED MEDICAL RESOURCES CORP.
ATTN: ANIL BHALANI
22872 AVENIDA EMPRESSA
RANCHO SANTA MARGARITA, CA 92688
510(k) NO: K012968
PHONE NO : 949-713-8327
DEVICE: APPLIED ACCESS SEAL
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

APPLIED MEDICAL TECHNOLOGY, INC.
ATTN: CHRIS ZANTOPULOS
15653 NEO PKWY.
CLEVELAND, OH 44128
510(k) NO: K012476
PHONE NO : 216-475-5577
DEVICE: MONARCH, TRANSSHAPING GASTROSTOMY TUBE MODEL 9-2010
SE DECISION MADE: 31-AUG-2001
510(k) STATEMENT

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

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

APPRIVA MEDICAL, INC.
HETER (WITH DILATOR), MODELS PL-12-12-09, PL-12-12-10
ATTN: MICHAEL KOLBER
777 NORTH PASTORIA AVE.
SUNNYVALE, CA 94086
510(k) NO: K012489
PHONE NO : 408-616-5203
DEVICE: MODIFICATION TO: X-SEPT TRANSSEPTAL SHEALTH AND TRANSITION CAT
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

AQUA WATER TREATMENT, INC.
ATTN: ANTHONY 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

AQUARIUS MEDICAL CORP.
ATTN: CHRISTINA M FLEMING
16047 NORTH 82ND ST.
SCOTTSDALE, AZ 85260
510(k) NO: K003368
PHONE NO : 480-991-1818
DEVICE: ACROTHERM
SE DECISION MADE: 19-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARC MEDICAL, INC. ATTN: HAL NORRIS 322 PATTERSON AVE. SCOTTDALE, GA 30079	510(k) NO: K011212 PHONE NO : 800-950-2720	DEVICE: FILTERFLO H SE DECISION MADE: 20-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARDO MEDICAL AG NATOR, MODEL 31.00.XX ATTN: EVA KRAHENBUHL GEWERBESTRASSE 19 UNTERAGERI,	510(k) NO: K011601 PHONE NO : 417 547 070 \	DEVICE: ARDO SUCTION PUMP MASTER, MODEL 30.00.XX; ARDO SUCTION PUMP SE SE DECISION MADE: 08-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARGOMEDICAL AG ATTN: DONALD A STEVENS 800 VINAL STREET, STE B-210 PITTSBURGH, PA 15212	510(k) NO: K010869 PHONE NO : 412-322-8280	DEVICE: EPOCA CUSTOM OFFSET SHOULDER SYSTEM SE DECISION MADE: 11-OCT-2001 510(k) STATEMENT
ARISTA LATINDO INDUSTRIAL, LTD. P. ATTN: LINGA SUMARTA 128 JALAN KYAI HAJI MUHAMMAD MANSYUR JAKARTA BARAT,	510(k) NO: K013320 PHONE NO : 622 166 20201195	DEVICE: BLUE LATEX EXAMINATION GLOVES, POWDER FREE SE DECISION MADE: 19-DEC-2001 510(k) STATEMENT
ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K003778 PHONE NO : 333 802 97401	DEVICE: BREAST-BOARD (MULTIPLE) SE DECISION MADE: 08-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K003779 PHONE NO : 333 802 97401	DEVICE: IMMOBILIZATION SYSTEM FOR ENT SE DECISION MADE: 12-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K004015 PHONE NO : 333 802 97401	DEVICE: BEAM BLOCK TRAYS SE DECISION MADE: 13-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE 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
ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K010062 PHONE NO : 333 802 97401	DEVICE: STYROFOAM CUTTERS FOR BLOCK CASTING SYSTEM SE DECISION MADE: 13-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA

ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K010063 PHONE NO : 333 802 97401	DEVICE: COUCH FOR TOTAL BODY RADIATION SE DECISION MADE: 02-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARPLAY MEDICAL S.A. ATTN: RICHARD BORGI 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K010172 PHONE NO : 333 802 97401	DEVICE: LEAD BLOCKS SE DECISION MADE: 18-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARPLAY MEDICAL S.A. ATTN: RICHARD BORJ 1, ROUTE DE CITEAUX IZEURE, COTE D'OR,	510(k) NO: K010174 PHONE NO : 333 802 97401	DEVICE: TRAY ADAPTERS, MULTIPLE SE DECISION MADE: 18-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARROW INTL., INC. ATTN: WILLIAM PAQUIN 9 PLYMOUTH ST. EVERETT, MA 02149	510(k) NO: K002256 PHONE NO : 617-389-6400	DEVICE: ARROW ACAT 2 INTRA-AORTIC BALLOON PUMP SE DECISION MADE: 03-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARROW INTL., INC. PORT ATTN: THOMAS D NICKEL 2400 BERNVILLE RD. READING, PA 19605	510(k) NO: K002507 PHONE NO : 610-478-3137	DEVICE: TWO-LUMEN CENTRAL VENOUS ACCESS KIT WITH HEMOSTASIS VALVE/SIDE SE DECISION MADE: 21-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARROW INTL., INC. -R950-U ATTN: WILLIAM PAQUIN 9 PLYMOUTH ST. EVERETT, MA 02149	510(k) NO: K010330 PHONE NO : 617-389-6400	DEVICE: ARROW REDIGUARD, 9FR. 50CC, INTRA-AORTIC BALLOON VATHETER, IAB SE DECISION MADE: 02-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARROW INTL., INC. ATTN: THOMAS D NICKEL 2400 BERNVILLE RD. READING, PA 19605	510(k) NO: K011056 PHONE NO : 610-478-3137	DEVICE: ARROW-TREROTOLA PERCUTANEOUS THROMBOLYTIC DEVICE OR "PTD" SE DECISION MADE: 24-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARROW INTL., INC. OBIAL SURFACE AND INTEGRAL HEMOSTASIS VALVE/SIDE PORT ATTN: THOMAS D NICKEL 2400 BERNVILLE RD. READING, PA 19605	510(k) NO: K011761 PHONE NO : 610-478-3137	DEVICE: MAC TWO-LUMEN CENTRAL VENOUS KIT WITH ARROWG ARD BLUE ANTIMICR SE DECISION MADE: 31-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTEMIS MEDICAL, INC. ATTN: ROBIN BUSH 655 MARINERS ISLAND BLVD. SUITE 303 SAN MATEO, CA 94404	510(k) NO: K003777 PHONE NO : 650-286-2999	DEVICE: CARIS SITE MARKER SE DECISION MADE: 06-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA

ARTERIA MEDICAL SCIENCE, INC. ATTN: STEVE CHERNOFF P.O. BOX 3515 REDMOND, WA 98073-3515	510(k) NO: K001917 PHONE NO : 425-861-8262	DEVICE: PARODI CATHETER FOR ANGIOGRAPHY (PARCA) SE DECISION MADE: 06-JUN-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
ARTHREX, INC. ATTN: VERNON BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K003227 PHONE NO : 941-643-5553	DEVICE: BIO-ABSORBABLE CORKSCREW MODEL AR-1920B SE DECISION MADE: 08-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. , 5.0 MM, ARTHREX TITANIUM CORKSCREW 6.5MM ATTN: VERNON C BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K003816 PHONE NO : 941-643-5553	DEVICE: ARTHREX TITANIUM CORKSCREW, 3.5 MM, ARTHREX TITANIUM CORKSCREW SE DECISION MADE: 09-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: VERNON BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K010124 PHONE NO : 941-643-5553	DEVICE: ARTHREX UNIVERS 30 SHOULDER PROSTHESIS SE DECISION MADE: 06-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: VERNON BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K010457 PHONE NO : 941-643-5553	DEVICE: ARTHREX TWISTLOC SUTURE ANCHOR, MODEL AR-1924 SE DECISION MADE: 14-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: VERNON BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K010525 PHONE NO : 941-643-5553	DEVICE: ARTHREX TENODESIS SCREW 7MM, 8MM, 9MM SE DECISION MADE: 23-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: BRETTE MASINO 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K010673 PHONE NO : 941-643-5553	DEVICE: ARTHREX FIBERWIRE, MODEL SPU-02NB-3800 SE DECISION MADE: 14-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: ANN WATERHOUSE 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K011007 PHONE NO : 941-643-5553	DEVICE: TENODESIS SCREW, 5.5 MM, MODEL AR-1350-55 SE DECISION MADE: 12-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA

ARTHREX, INC.
ATTN: VERNON BROWN
2885 SOUTH HORSESHOE DR.
NAPLES, FL 34104
510(k) NO: K011172
PHONE NO : 941-643-5553
DEVICE: ARTHREX BIO-TRANSFIX
SE DECISION MADE: 19-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHREX, INC.
ATTN: ANN WATERHOUSE
2885 SOUTH HORSESHOE DR.
NAPLES, FL 34104
510(k) NO: K011495
PHONE NO : 941-643-5553
DEVICE: ARTHREX BIO-POST AND WASHER
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHREX, INC.
ATTN: ANN WATERHOUSE
2885 SOUTH HORSESHOE DR.
NAPLES, FL 34104
510(k) NO: K012923
PHONE NO : 941-643-5553
DEVICE: ARTHREX FIBERWIRE, USP SIZE 5, MODEL AR-7201
SE DECISION MADE: 04-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
ATTN: BETTY M JOHNSON
595 NORTH PASTORIA AVE.
SUNNYVALE, CA 94086
510(k) NO: K010568
PHONE NO : 408-736-0224
DEVICE: ARTHROCARE UROLOGY ELECTROSURGERY SYSTEM
SE DECISION MADE: 27-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
ATTN: BRUCE PROTHRO
595 NORTH PASTORIA AVE.
SUNNYVALE, CA 94086
510(k) NO: K010811
PHONE NO : 408-736-0224
DEVICE: PERC-D SPINEWAND
SE DECISION MADE: 30-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
RD & ARTHROCARE ARTHROWAND
ATTN: BRUCE PROTHRO
595 NORTH PASTORIA AVE.
SUNNYVALE, CA 94086
510(k) NO: K011083
PHONE NO : 408-736-0224
DEVICE: ARTHROCARE SYSTEM 2000 CONTROLLER, CABLE, FOOTSWITCH, POWER CC
SE DECISION MADE: 28-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
ATTN: BRUCE PROTHRO
595 NORTH PASTORIA AVE.
SUNNYVALE, CA 94085-2936
510(k) NO: K011279
PHONE NO : 408-736-0224
DEVICE: ENTEC EVAC PLASMA WAND
SE DECISION MADE: 19-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
970-02; FOOTSWITCH, MODEL H2000-04; POWERCORD, MODEL H2000
ATTN: BETTY M JOHNSON
595 NORTH PASTORIA AVE.
SUNNYVALE, CA 94085-2936
510(k) NO: K011634
PHONE NO : 408-736-0224
DEVICE: ARTHROCARE CONTROLLER, MODEL H2000; ARTHROCARE CABLE, MODEL HO
SE DECISION MADE: 19-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
ATTN: BRUCE PROTHRO
595 NORTH PASTORIA AVE.
SUNNYVALE, CA 94085-2936
510(k) NO: K012519
PHONE NO : 408-736-0224
DEVICE: ARTHROCARE ELECTROSURGERY WANDS
SE DECISION MADE: 25-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP. ATTN: BRUCE PROTHRO 595 NORTH PASTORIA AVE. SUNNYVALE, CA 94085-2936	510(k) NO: K013463 PHONE NO : 408-736-0224	DEVICE: ARTHROCARE ARTHRO WANDS, ENETEC EVAC PLASMA WAND SE DECISION MADE: 15-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTHROTEK, INC. ATTN: SARA B SHULTZ 56 EAST BELLE DRIVE P.O. BOX 587 WARSAW, IN 46582	510(k) NO: K012872 PHONE NO : 219-267-6639	DEVICE: RESORBABLE SCREW ANCHOR SE DECISION MADE: 20-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ARTSCAN MEDICAL INNOVATIONS ATTN: ROBERT ANTHONY 4804 OTN OAK ROAD AKRON, OH 44333	510(k) NO: K010303 PHONE NO : 330-666-6992	DEVICE: ARTSCAN CARTILAGE STIFFNESS TESTING DEVICE SE DECISION MADE: 11-SEP-2001 510(k) SUMMARY AVAILABLE FROM FDA
ASIA-MED GMBH AND CO KG X) ATTN: KEVIN WALLS 13 RED FOX LANE LITTLETON, CO 80127	510(k) NO: K011808 PHONE NO : 720-962-5412	DEVICE: ASIA-MED ACUPUNCTURE NEEDLES, (STANDARD, SPECIAL, COMPACT, APE SE DECISION MADE: 10-JUL-2001 510(k) STATEMENT
ASPECT MEDICAL SYSTEMS, INC. ATTN: CHRISTINE M VOZELLA 141 NEEDHAM STREET NEWTON, MA 02464	510(k) NO: K011534 PHONE NO : 617-559-7028	DEVICE: EEG MIS MONITOR MODEL # A-2000; BIS ENGINE SE DECISION MADE: 15-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ASPECT MEDICAL SYSTEMS, INC. ATTN: CHRISTINE M VOZELLA 141 NEEDHAM STREET NEWTON, MA 02464	510(k) NO: K011834 PHONE NO : 617-559-7400	DEVICE: BIS ENGINE SE DECISION MADE: 10-JUL-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
ASTRA TECH, INC. ATTN: NIKLAS LIDSKOG 430 BEDFORD STREET SUITE 100 LEXINGTON, MA 02420	510(k) NO: K002513 PHONE NO : 781-861-7707	DEVICE: ASTRA TECH IMPLANTS - DENTAL SYSTEM SE DECISION MADE: 04-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ASTRA TECH, INC. ATTN: BRUCE R MANNING 96 WEST MAIN STREET NORTHBOROUGH, MA 01532	510(k) NO: K012374 PHONE NO : 508-393-3100	DEVICE: MODIFICATION TO: LOFRIC PLUS SINGLE USE URINARY CATHETER SE DECISION MADE: 23-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

ASTRA TECH, INC. ATTN: BRUCE R MANNING 96 WEST MAIN STREET NORTHBOROUGH, MA 01532	510(k) NO: K012965 PHONE NO : 508-393-3100	DEVICE: ASTRA TECH IMPLANTS-DENTAL SYSTEM SE DECISION MADE: 19-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
ATC TECHNOLOGIES, INC. ATTN: PAUL KIERCE 80 CUMMINGS PARK WOBURN, MA 01801	510(k) NO: K010473 PHONE NO : 781-939-0725	DEVICE: SPARROWHAWK DISPOSABLE SE DECISION MADE: 06-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
ATLANTECH MEDICAL DEVICES LTD. ATTN: NICK WOODS 38 FREEMANS WAY HARROGATE, NORTH YORKSHIRE,	510(k) NO: K013334 PHONE NO : 44 142 3888806	DEVICE: ENDOFLIP SE DECISION MADE: 13-DEC-2001 510(k) STATEMENT
ATRICURE, INC. ATTN: MARK L FRIEDMAN 6033 SCHUMACHER PARK DRIVE WEST CHESTER, OHIO, OH 45069	510(k) NO: K011722 PHONE NO : 513-755-4105	DEVICE: ATRICURE BIPOLAR COAGULATION SYSTEM SE DECISION MADE: 30-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
ATRIUM MEDICAL CORP. ATTN: REBECCA DOLLOFF 5 WENTWORTH DR. HUDSON, NH 03051	510(k) NO: K002627 PHONE NO : 603-880-1433	DEVICE: ATRIUM MEDICAL CORPORATION CLEARWAY PTFE BALLOON CATHETER SE DECISION MADE: 26-APR-2001 510(k) STATEMENT
ATRIUM MEDICAL CORP. ATTN: KAREN HALL 5 WENTWORTH DR. HUDSON, NH 03051	510(k) NO: K010516 PHONE NO : 603-880-1433	DEVICE: ADVANTA SST GRAFT (> 6MM) SE DECISION MADE: 18-MAY-2001 510(k) STATEMENT
ATRIUM MEDICAL CORP. ATTN: KAREN HALL 5 WENTWORTH DR. HUDSON, NH 03051	510(k) NO: K010517 PHONE NO : 603-880-1433	DEVICE: ADVANTA SST GRAFT (<6MM) SE DECISION MADE: 18-MAY-2001 510(k) STATEMENT
ATYS MEDICAL ATTN: CHRISTINE TURLAT 17, PARC D' ARBORA SOUCIEU EN JARREST,	510(k) NO: K012369 PHONE NO : 33 4 78056969	DEVICE: BASIC, MODELS BASIC 1, BASIC 2, AND BASIC 3 SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
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

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
AUTO-LOCK ATTN: DIETRICH W GRABIS 58 OAKDALE AVE. SAN RAFAEL, CA 94901	510(k) NO: K010477 PHONE NO : 415-454-8054	DEVICE: AUTO-LOCK SE DECISION MADE: 09-OCT-2001 510(k) STATEMENT
AUTO/CATH VASCULAR ACCESS, INC. ATTN: ANIL BHALANI 21092 BAKE PARKWAY SUITE 110 LAKE FOREST, CA 92630	510(k) NO: K003187 PHONE NO : 949-206-9911	DEVICE: VACUCATH I.V. CATHETER INTRODUCTER SE DECISION MADE: 21-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
AUTOGENESIS, INC. ATTN: JAMES EDWARDS 8700 OLD HARFORD RD. BALTIMORE, MD 21234	510(k) NO: K013818 PHONE NO : 410-665-2017	DEVICE: AUTOGENESIS AUTOMATOR, MODEL M1000 SE DECISION MADE: 05-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
AUTOMATIC MEDICAL TECHNOLOGIES, IN ATTN: MICHAEL MITSUNAGA 3422 WEST PICO BLVD. LOS ANGELES, CA 90019	510(k) NO: K002409 PHONE NO : 323-735-3811	DEVICE: MAXONE, BLOOD, BLOOD PRODUCTS AND IV FLUID WARMER SE DECISION MADE: 28-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
AVANTA ORTHOPAEDICS, INC. ATTN: LOUISE M FOCHT 9369 CARROLL PARK RD., SUITE A SAN DIEGO, CA 92121	510(k) NO: K003033 PHONE NO : 858-452-8580	DEVICE: SCAPHIX, STAPLE, FIXATION, BONE SE DECISION MADE: 30-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
AVANTA ORTHOPAEDICS, INC. ATTN: LOUISE M FOCHT 9369 CARROLL PARK RD., SUITE A SAN DIEGO, CA 92121	510(k) NO: K010786 PHONE NO : 858-452-8580	DEVICE: ULNAR HEAD IMPLANT SE DECISION MADE: 11-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
AVANTA ORTHOPAEDICS, INC. ATTN: LOUISE M FOCHT 9369 CARROLL PARK RD., SUITE A SAN DIEGO, CA 92121	510(k) NO: K010847 PHONE NO : 858-452-8580	DEVICE: K'FIX SE DECISION MADE: 19-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
AVANTA ORTHOPAEDICS, INC. ATTN: LOUISE M FOCHT 9369 CARROLL PARK RD., SUITE A SAN DIEGO, CA 92121	510(k) NO: K011819 PHONE NO : 858-452-8580	DEVICE: RADIAL HEAD IMPLANT SE DECISION MADE: 19-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA

AVID CARE CORP.
ATTN: WILLIAM GENTHE
152 WEST WISCONSIN AVE.
SUITE 930
MILWAUKEE, WI 53203

510(k) NO: K010029
PHONE NO : 414-291-0844

DEVICE: HOME HEALTH MONITORING SYSTEM
SE DECISION MADE: 29-JUN-2001

510(k) SUMMARY AVAILABLE FROM FDA

AVID CARE CORP.
ATTN: JONATHAN S KAHAN
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109

510(k) NO: K011779
PHONE NO : 202-637-5794

DEVICE: AVIDCARE SERIES 100 TELEMANAGEMENT SYSTEM
SE DECISION MADE: 13-JUL-2001
510(k) STATEMENT

AVID N.I.T., INC.
NIT METAL HUB LUTZ EPIDURAL NEEDLE, MODEL RM2035L
ATTN: SCOTT HENDERSON
390 SCARLET BLVD.
OLDSMAR, FL 34677

510(k) NO: K013231
PHONE NO : 813-818-8705

DEVICE: AVID-NIT PLASTIC HUB LUTZ EPIDURAL NEEDLE,MODEL RP2035L, AVID-

SE DECISION MADE: 03-DEC-2001
510(k) STATEMENT

AVITA INTERNATIONAL CORP.
ATTN: ALLEN REICH
900 N. SWITZER CANYON DR. #142
FLAGGSTAFF, AZ 86001

510(k) NO: K010462
PHONE NO : 520-773-9488

DEVICE: AVITA PICCOLO/EXATO INFARED EAR THERMOMETER (TS2 & TS4 SERIES)

SE DECISION MADE: 11-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

AVITA INTERNATIONAL CORP.
ATTN: ALLEN REICH
900 N. SWITZER CANYON DR. #142
FLAGGSTAFF, AZ 86001

510(k) NO: K012136
PHONE NO : 520-773-9488

DEVICE: AVITA AGIL IT 101 INSTANT DIGITAL THERMOMETER
SE DECISION MADE: 10-SEP-2001
510(k) SUMMARY AVAILABLE FROM FDA

AWARENESS TECHNOLOGY, INC.
ATTN: MARY FREEMAN
1995 S.W. MARTIN HWY.
P.O. BOX 1679
PALM CITY, FL 34990

510(k) NO: K010877
PHONE NO : 561-283-6540

DEVICE: CHEMWELL, MODEL 2900
SE DECISION MADE: 23-MAY-2001

510(k) STATEMENT

AXIOM WORLDWIDE, INC.
ATTN: JIM GIBSON
3830 GUNN HWY.
TAMPA, FL 33364

510(k) NO: K010292
PHONE NO : 813-969-2414

DEVICE: DRX 2000
SE DECISION MADE: 01-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

AXON SYSTEMS, INC.
ATTN: HOWARD BAILIN
400-2200 OSER AVE.
HAUPPAUGE, NY 11788

510(k) NO: K010697
PHONE NO : 631-436-5112

DEVICE: UNIQUE AMBULATORY EEG
SE DECISION MADE: 06-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K003971
PHONE NO : 609-924-9510

DEVICE: AXYA MEDICAL, INC. MODEL 1000 AXYALOOP BONE ANCHOR
SE DECISION MADE: 21-MAR-2001

510(k) SUMMARY AVAILABLE FROM FDA

AXYA MEDICAL, INC. ATTN: HOWARD L SCHRAYER 100 CUMMINGS CENTER SUITE 444C BEVERLY, MA 01915	510(k) NO: K011912 PHONE NO : 609-924-9510	DEVICE: MODEL 2000 AXYALOOP SELF-TAPPING BONE ANCHOR, MODEL 2000 SE DECISION MADE: 31-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
B BRAUN NA TECH LP CAVE FILTER ATTN: PAUL O'CONNELL 2934 CENTRAL STREET, SUITE 1A EVANSTON, IL 60201	510(k) NO: K010485 PHONE NO : 847-733-8900	DEVICE: VENA TECH VENA CAVA FILTER; VENA TECH 30D VENA CAVA FILTER; VE SE DECISION MADE: 18-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
B-K MEDICAL A/S ATTN: VILLY BRAENDER SANDTOFTEN 9 GENTOFTE,	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
B-K MEDICAL A/S ATTN: VILLY BRAENDER SANDTOFTEN 9 GENTOFTE,	510(k) NO: K003986 PHONE NO : 011 454 5970100	DEVICE: ULTRASOUND SCANNER TYPE 2102 SE DECISION MADE: 03-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
B-K MEDICAL A/S ATTN: VILLY BRAENDER SANDTOFTEN 9 GENTOFTE,	510(k) NO: K011417 PHONE NO : 011 454 5970100	DEVICE: ULTRASOUND SCANNER, TYPE 2102 SE DECISION MADE: 08-JUN-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
BACCHUS VASCULAR, INC. ATTN: ROBERT A CLARK 3110 CORONADO DR. SANTA CLARA, CA 95054	510(k) NO: K003570 PHONE NO : 408-980-8300	DEVICE: BACCHUS THROMBECTOMY CATHETER (BTC), MODEL BTC-0755 SE DECISION MADE: 06-JUN-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
BARRIERMED, INC. ATTN: CARLO PONCIPE 2500 WEST LAKE MARY BLVD. LAKE MARY, FL 32746	510(k) NO: K011446 PHONE NO : 407-323-1604	DEVICE: BARRIERPLUS POWDER-FREE SYNTHETIC POLYISOPRENE SURGICAL GLOVES SE DECISION MADE: 14-JUN-2001 510(k) STATEMENT

BASIC DENTAL IMPLANT SYSTEMS, INC. 510(k) NO: K001259
DEVICE: 2-PIECE POST AND CORE FOR THE B.A.S.I.C. DENTAL IMPLANT SYSTEM

ATTN: DAN BLACKLOCK PHONE NO : 505-881-1376
3321 COLUMBIA, N.E.
ALBUQUERQUE, NM 87107-2001
SE DECISION MADE: 12-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BASIC DENTAL IMPLANT SYSTEMS, INC. 510(k) NO: K012299
DEVICE: MODIFICATION TO: STRAIGHT POST AND CORE II FOR THE BASIC DENTA
L IMPLANT SYSTEM
ATTN: DAN BLACKLOCK PHONE NO : 505-881-1376
3321 COLUMBIA, N.E.
ALBUQUERQUE, NM 87107-2001
SE DECISION MADE: 01-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BASIC DENTAL IMPLANT SYSTEMS, INC. 510(k) NO: K013682
ATTN: DAN BLACKLOCK PHONE NO : 505-881-1376
3321 COLUMBIA, N.E.
ALBUQUERQUE, NM 87107-2001
DEVICE: MODIFICATION TO BASIC DENTAL IMPLANT SYSTEM
SE DECISION MADE: 28-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

BASIC SOLUTIONS, LLC. 510(k) NO: K001859
ATTN: JAY H GELLER PHONE NO : 310-449-1399
2425 W. OLYMPIC BOULEVARD
WEST TOWER, SUITE 4000
SANTA MONICA, CA 90404
DEVICE: PENILE CONSTRICTOR RING
SE DECISION MADE: 11-JAN-2001
510(k) STATEMENT

BAUMER S.A. 510(k) NO: K003975
ATTN: BRENO C FARAGO PHONE NO : 551 938 063030
AV. PREF. ANTONIO TAVARES
LEITE NR: 181
MOGI MIRIM, SAO PAULO,
DEVICE: BAUMER CEMENTED HIP PROSTHESIS
SE DECISION MADE: 19-MAR-2001
510(k) STATEMENT

BAUMER S.A. 510(k) NO: K003976
ATTN: BRENO C FARAGO PHONE NO : 551 938 063030
AV. PREF. ANTONIO TAVARES
LEITE NR: 181
MOGI MIRIM, SAO PAULO,
DEVICE: BAUMER MULLER HIP PROSTHESIS
SE DECISION MADE: 19-MAR-2001
510(k) STATEMENT

BAUMER S.A. 510(k) NO: K011504
ATTN: BRENO CORREA FARAGO JR. PHONE NO : 551 938 063030
AV. PREF. ANTONIO TAVARES
LEITE NR: 181
MOGI MIRIM, SAO PAULO,
DEVICE: BAUMER LOCKING NAIL
SE DECISION MADE: 14-AUG-2001
510(k) STATEMENT

BAUSCH & LOMB, INC. 510(k) NO: K010260
ATTN: PAUL S KRAMSKY PHONE NO : 949-454-4485
9342 JERONIMO ROAD
IRVINE, CA 92618
DEVICE: HANSATOME MICROKERATOME
SE DECISION MADE: 27-APR-2001
510(k) STATEMENT

BAUSCH & LOMB, INC. ATTN: DOUGLAS J FORTUNATO 1400 N.GOODMAN STREET ROCHESTER, NY 14692-0450	510(k) NO: K011199 PHONE NO : 716-338-5477	DEVICE: PROVIEW EYE PRESSURE MONITOR SE DECISION MADE: 02-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB, INC. LITY TINTED CONTACT ATTN: DEBRA KETCHUM 1400 NORTH GOODMAN STREET P.O. BOX 450 ROCHESTER, NY 14692	510(k) NO: K011718 PHONE NO : 716-338-8638	DEVICE: BAUSCH & LOMB SOFLENS ONE DAY DISPOSABLE (HILAFILCON A) VISIBI SE DECISION MADE: 25-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB, INC. ATTN: PAUL G STAPLETON 1400 NORTH GOODMAN ST. ROCHESTER, NY 14603	510(k) NO: K011796 PHONE NO : 716-338-8172	DEVICE: RENU MULTIPLUS NO RUB MULTI-PURPOSE SOLUTION SE DECISION MADE: 01-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB, INC. ATTN: VANADA JOHNSON 3365 TREE COURT INDUSTRIAL BLV ST. LOUIS, MO 63122-6694	510(k) NO: K012435 PHONE NO : 636-226-3182	DEVICE: ENTRY SITE ALIGNMENT SYSTEM MODEL # CX9626 SE DECISION MADE: 02-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB, INC. ATTN: PENNI L PANNELL 9342 JERONIMO RD. IRVINE, CA 92718	510(k) NO: K012873 PHONE NO : 949-454-4530	DEVICE: DOCUMENTING LASER SLIT LAMP, DP 2010 SE DECISION MADE: 19-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB, INC. ATTN: KIM S DEVITTO 1400 NORTH GOODMAN ST. P.O. BOX 30450 ROCHESTER, NY 14603-0450	510(k) NO: K013232 PHONE NO : 716-338-6401	DEVICE: CYBERCASES BY BAUSCH & LOMB SE DECISION MADE: 20-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAXA CORP. ATTN: CARL STEINECK 13760 EAST ARAPAHOE RD. ENGLEWOOD, CO 80112	510(k) NO: K002705 PHONE NO : 303-617-2181	DEVICE: EXACTA-MIX 2400 COMPOUNDING SYSTEM, MODEL EXACTA-MIX 2400 SE DECISION MADE: 28-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
BAXTER HEALTHCARE CORP. ATTN: ARLENE VIDOR 550 NORTH BRAND BOULEVARD GLENDALE, CA 91023	510(k) NO: K003747 PHONE NO : 818-507-5523	DEVICE: C1-INHIBITOR MICROTITER ASSAY DEVICE SE DECISION MADE: 19-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA

BAXTER HEALTHCARE CORP. ATTN: JENNIFER M PAINE RT. 120 & WILSON RD. ROUND LAKE, IL 60073	510(k) NO: K010566 PHONE NO : 847-270-5825	DEVICE: COLLEAGUE VOLUMETRIC INFUSION PUMP SE DECISION MADE: 15-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAXTER HEALTHCARE CORP. AIN MANAGEMENT SYSTEM ATTN: VICKI L DREWS RT. 120 AND WILSON ROAD ROUND LAKE, IL 60073-0490	510(k) NO: K011317 PHONE NO : 847-270-5916	DEVICE: MULTIRATE INFUSOR SV; MULTIRATE INFUSER LV; BAXTER PAIN MATE P SE DECISION MADE: 28-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAXTER HEALTHCARE CORP. 5C8310, 5C8302, 5C4471, 5C4469 ATTN: DAVID E CURTIN 1620 WAUKEGAN RD. MPGR-A2E MCGAW PARK, IL 60085	510(k) NO: K012988 PHONE NO : 847-473-6079	DEVICE: HOMECHOICE PERSONAL CYCLER PERITONEAL DIALYSIS SYSTEM, MODELS SE DECISION MADE: 05-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: WILLIAM J PIGNATO 63 NORTH ST. MEDFIELD, MA 02052-1688	510(k) NO: K003412 PHONE NO : 508-359-3825	DEVICE: ADVIA CENTAUR RUBELLA IGG ASSAY SE DECISION MADE: 13-APR-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
BAYER CORP. ATTN: FREDICK CLERIE 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K010201 PHONE NO : 914-524-3494	DEVICE: BAYER ADVIA IMS SYSTEM SE DECISION MADE: 29-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: WILLIAM J PIGNATO 63 NORTH ST. MEDFIELD, MA 02052-1688	510(k) NO: K010668 PHONE NO : 508-359-3825	DEVICE: BAYER DIAGNOSTICS ADVIA CENTAUR RUBELLA IGM ASSAY SE DECISION MADE: 05-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: WILLIAM J PIGNATO 63 NORTH ST. MEDFIELD, MA 02052-1688	510(k) NO: K010755 PHONE NO : 508-359-3825	DEVICE: BAYER DIAGNOSTICS ADVIA CENTAUR TOXOPLASMA IGM ASSAY SE DECISION MADE: 20-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K011963 PHONE NO : 914-524-2446	DEVICE: ADVIA 1650 GLUCOSE HEXOKINASE 11 ASSAY SE DECISION MADE: 20-NOV-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 CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K012337 PHONE NO : 914-524-2446	DEVICE: BAYER ADVIA IMS SYSTEM; C-REACTIVE PROTEIN SYSTEM SE DECISION MADE: 06-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K012340 PHONE NO : 914-524-2446	DEVICE: BAYER ADVIA SYSTEM; UNSATURATED IRON BINDING CAPACITY (UIBC) SE DECISION MADE: 01-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K012777 PHONE NO : 914-524-2446	DEVICE: ACS: 180 AND ADVIA CENTAUR ANTI-THYROGLOBULIN IMMUNOASSAYS SE DECISION MADE: 22-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K013272 PHONE NO : 914-524-2446	DEVICE: ACS: 180 AND ADVIA CENTAUR THEOPHYLLINE 2 ASSAY SE DECISION MADE: 25-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE. TARRYTOWN, NY 10591-5097	510(k) NO: K013568 PHONE NO : 914-524-2446	DEVICE: CEA ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEM SE DECISION MADE: 21-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER DIAGNOSTICS CORP. ATTN: THOMAS F FLYNN 63 NORTH STREET MEDFIELD, MA 02052	510(k) NO: K010050 PHONE NO : 508-359-3825	DEVICE: ADVIA CENTAUR AND ACS: 180 FOLATE IMMUNOASSAY SE DECISION MADE: 05-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BAYER DIAGNOSTICS CORP. ATTN: BARBARA PREISEL-SIMMONS 63 NORTH STREET MEDFIELD, MA 02052	510(k) NO: K012183 PHONE NO : 508-359-7711	DEVICE: BAYER DIAGNOSTICS ADVIA CENTAUR TOXOPLASMA IGG ASSAY SE DECISION MADE: 27-DEC-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
BAYER DIAGNOSTICS CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE TARRYTOWN, NY 10591-5097	510(k) NO: K013406 PHONE NO : 914-524-2446	DEVICE: ADVIA CENTAUR HOMOCYSTEINE ASSAY SE DECISION MADE: 18-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA

BAYER DIAGNOSTICS CORP.
ATTN: KENNETH T EDDS
511 BENEDICT AVE
TARRYTOWN, NY 10591-5097

510(k) NO: K013606
PHONE NO : 914-524-2446

DEVICE: ACS 180 HOMOCYSTEINE ASSAY
SE DECISION MADE: 21-DEC-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

BAYLIS MEDICAL CO., INC.
USE), PMG-230 (FOR INTERNATIONAL USE)
ATTN: KRIS SHAH
5160 EXPLORER DRIVE, UNIT 5
MISSISSAUGA,

510(k) NO: K002565
PHONE NO :

DEVICE: BAYLIS PAIN MANAGEMENT GENERATOR MODEL: PMG-115 (FOR DOMESTIC

SE DECISION MADE: 03-MAY-2001
510(k) STATEMENT

BAYLIS MEDICAL CO., INC.
ATTN: KRIS SHAH
5160 EXPLORER DRIVE, UNIT 33
MISSISSAUGA,

510(k) NO: K010265
PHONE NO : 905 602 4875

DEVICE: BAYLIS MEDICAL RF PERFORATION PROBE, MODEL RFP-265
SE DECISION MADE: 09-APR-2001
510(k) STATEMENT

BCI, INC.
ATTN: DONALD ALEXANDER
N7 W22025 JOHNSON ROAD
WAUKESHA, WI 53186

510(k) NO: K010770
PHONE NO : 262-542-3100

DEVICE: BCI ADVISOR VITAL SIGNS MONITOR (9200)
SE DECISION MADE: 12-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BCI, INC.
ATTN: DONALD ALEXANDER
N7 W22025 JOHNSON ROAD
WAUKESHA, WI 53186

510(k) NO: K011156
PHONE NO : 262-542-3100

DEVICE: BCI 3403 SLEEP SCREENING PULSE OXIMETER
SE DECISION MADE: 14-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BCI, INC.
ATTN: DONALD J ALEXANDER
N7 W22025 JOHNSON ROAD
WAUKESHA, WI 53186

510(k) NO: K011177
PHONE NO : 262-542-3100

DEVICE: BCI ADVISOR VITAL SIGNS MONITOR (9200)
SE DECISION MADE: 23-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD
ATTN: GREG W MORGAN
1 BECTON DR. MC 226
FRANKLIN LAKES, NJ 07417

510(k) NO: K011103
PHONE NO : 201-847-4344

DEVICE: BD SPRING BASED SYRINGE
SE DECISION MADE: 13-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD
ATTN: GREGORY W MORGAN
1 BECTON DR. MC 226
FRANKLIN LAKES, NJ 07417

510(k) NO: K011858
PHONE NO : 201-847-4344

DEVICE: INTERLINK THREADED LOCK CANNULA
SE DECISION MADE: 19-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD
E
ATTN: GREGORY W MORGAN
ONE BECTON DRIVE MC226
FRANKLIN LAKES, NJ 07417

510(k) NO: K011982
PHONE NO : 201-847-4344

DEVICE: 0.9% SODIUM CHLORIDE INJECTION, USP BD PRE-FILLED FLUSH SYRING
SE DECISION MADE: 17-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD
/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: BD DURASAFE PLUS EPIDURAL LOCK CSE NEEDLE SET
SE DECISION MADE: 06-SEP-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD BECTON DICKINSON VACUTAINER SYS
ATTN: DENNIS R MERTZ
7 LOVETON CIR.
SPARKS, MD 21152-0999

510(k) NO: K003062
PHONE NO : 410-316-4192

DEVICE: BACTEC MGIT 960 SIR KITS
SE DECISION MADE: 06-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD BECTON DICKINSON VACUTAINER SYS
ATTN: M. WENDY BOSSHARDT
1 BECTON DR.
FRANKLIN LAKES, NJ 07417-1880

510(k) NO: K003461
PHONE NO : 201-847-6280

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

BD BECTON DICKINSON VACUTAINER SYS
E
ATTN: GREGORY W MORGAN
1 BECTON DRIVE
MAIL CODE 226
FRANKLIN LAKES, NJ 07417

510(k) NO: K003553
PHONE NO : 201-847-4344

DEVICE: 0.9% SODIUM CHLORIDE INJECTION, USP BD PRE-FILLED FLUSH SYRING
SE DECISION MADE: 21-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BD MEDICAL SYSTEMS
ATTN: GREG W MORGAN
1 BECTON DRIVE MC226
FRANKLIN LAKES, NJ 07417

510(k) NO: K010188
PHONE NO : 201-847-4344

DEVICE: BD ECLIPSE HYPODERMIC NEEDLE
SE DECISION MADE: 01-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
SYSTEMS, MODEL 34470,34475,34479
ATTN: DENISE THOMPSON
1000 LAKE HAZELTINE DR.
CHASKA, MN 55318-1084

510(k) NO: K003259
PHONE NO : 612-368-1202

DEVICE: ACCESS TOXO IGM II REAGENTS FOR USE ON THE ACCESS IMMUNOASSAY
SE DECISION MADE: 13-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ATTN: STAN SUGRUE
11800 SW 147TH AVE.
MIAMI, FL 33196-2500

510(k) NO: K010064
PHONE NO : 305-380-4552

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

BECKMAN COULTER, INC.
ATTN: STAN SUGRUE
11800 SW 147TH AVE.
MIAMI, FL 33196-2500

510(k) NO: K010066
PHONE NO : 305-380-4552

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

BECKMAN COULTER, INC. EIN (CRPH) REAGENT ATTN: ANNETTE HELLIE 200 SOUTH KRAEMER BLVD. BREA, CA 92822	510(k) NO: K010236 PHONE NO : 714-993-8767	DEVICE: IMMAGE IMMUNOCHEMISTRY SYSTEM HIGH SENSITIVITY C-REACTIVE PROI SE DECISION MADE: 05-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: ANNETTE HELLIE 200 SOUTH KRAEMER BLVD. BREA, CA 92822	510(k) NO: K010358 PHONE NO : 714-993-8767	DEVICE: VIGIL SEROLOGY CONTROL LEVEL C SE DECISION MADE: 05-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: BRENT TABER 1000 LAKE HAZELTINE DR. CHASKA, MN 55318-1084	510(k) NO: K010428 PHONE NO : 952-368-1323	DEVICE: ACCUTNI QC ON THE ACCESS IMMUNOASSAY SYSTEM #33349 SE DECISION MADE: 13-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. EM # 33340, 33345 ATTN: BRENT TABER 1000 LAKE HAZELTINE DR. CHASKA, MN 55318-1084	510(k) NO: K010429 PHONE NO : 952-368-1323	DEVICE: ACCUTNI AND ACCUTNI CALIBRATORS ON THE ACCESS IMMUNOASSAY SYST SE DECISION MADE: 05-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. REAGENT ATTN: ANNETTE HELLIE 200 SOUTH KRAEMER BLVD. BREA, CA 92822	510(k) NO: K010597 PHONE NO : 714-993-8767	DEVICE: SYNCHRON LX SYSTEMS HIGH SENSITIVITY C-REACTIVE PROTIEN (CRPH) SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: RICHARD T ROSS, RAC 200 SOUTH KRAEMER BLVD.,W-104 BREA, CA 92822-8000	510(k) NO: K010693 PHONE NO : 714-961-4912	DEVICE: VIGIL DNASE B CONTROL SE DECISION MADE: 11-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: RICHARD T ROSS 200 SOUTH KRAEMER BLVD.,W-104 BREA, CA 92822-8000	510(k) NO: K010696 PHONE NO : 714-961-4912	DEVICE: BECKMAN COULTER DNASE B CALIBRATOR SE DECISION MADE: 10-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: MARY BETH TANG 200 SOUTH KRAEMER BLVD.,W-104 BREA, CA 92822-8000	510(k) NO: K010748 PHONE NO : 714-961-3777	DEVICE: SYNCHRON SYSTEMS HEMOGLOBIN A1C REAGENT SE DECISION MADE: 10-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ER, MODEL 6605526 ATTN: STAN SUGRUE 11800 S.W. 14TH AVENUE P.O.BOX 169015; MC 31-B06 MIAMI, FL 33116-9015	510(k) NO: K010765 PHONE NO : 305-380-4552	DEVICE: COULTER HMX ANALYZER, MODEL 6605523, COULTER HMX WITH AUTOLOAD SE DECISION MADE: 13-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ATTN: ANNETTE HELLIE
200 SOUTH KRAEMER BLVD.
BREA, CA 92822

510(k) NO: K011213
PHONE NO : 714-993-8767

DEVICE: MODIFICATION TO SYNCHRON LX 20 CLINICAL CHEMISTRY SYSTEM
SE DECISION MADE: 16-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ATTN: STAN SUGRUE
11800 SW 147TH AVE.
MIAMI, FL 33196-2500

510(k) NO: K011342
PHONE NO : 305-380-4552

DEVICE: COULTER LH 750 HEMATOLOGY ANALYZER, MODEL 6605632
SE DECISION MADE: 09-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
PRO, CX9 PRO
ATTN: MARY B TANG
200 SOUTH KRAEMER BLVD.,W-104
BREA, CA 92822-8000

510(k) NO: K011465
PHONE NO : 714-961-3777

DEVICE: SYNCHRON CX PRO CLINICAL SYSTEMS, MODEL CX4 PRO, CX5 PRO, CX7
SE DECISION MADE: 08-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
MUNOASSAY 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

BECKMAN COULTER, INC.
ATTN: MARA CALER
1000 LAKE HAZELTINE DR.
CHASKA, MN 55318-1084

510(k) NO: K012900
PHONE NO : 858-621-4583

DEVICE: ACCESS UNCONJUGATED ESTRIOL CALIBRATORS
SE DECISION MADE: 16-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
IN CALIBRATOR
ATTN: MARY BETH TANG
200 SOUTH KRAEMER BLVD.,W-104
BREA, CA 92822-8000

510(k) NO: K013076
PHONE NO : 714-961-3777

DEVICE: SYNCHRON SYSTEMS VANCOMYCIN REAGENT; SYNCHRON SYSTEMS VANCOMYC
SE DECISION MADE: 12-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ATTN: MARY BETH TANG
200 SOUTH KRAEMER BLVD.
BREA, CA 92822

510(k) NO: K013235
PHONE NO : 714-961-3777

DEVICE: MODIFICATION TO SYNCHRON CONTROL
SE DECISION MADE: 16-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ATTN: LOURDES COBA
11800 SW 147TH AVENUE
MIAMI, FL 33196-2500

510(k) NO: K013842
PHONE NO : 305-380-4079

DEVICE: IMMUNO-TROL LOW CELLS
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ND LX20 PRO)
ATTN: ANNETTE HELLIE
200 SOUTH KRAEMER BLVD.
BREA, CA 92822

510(k) NO: K014034
PHONE NO : 714-993-8767

DEVICE: MODIFICATION TO SYNCHRON LX CLINICAL CHEMISTRY SYSTEMS (LX20 A
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECTON DICKINSON & CO. 510(k) NO: K011984 DEVICE: BD VACUTAINER PUSH BUTTON BLOOD COLECTION SET
ATTN: M. WENDY BOSSHARDT PHONE NO : 201-847-6280 SE DECISION MADE: 29-AUG-2001
1 BECTON DRIVE 510(k) SUMMARY AVAILABLE FROM FDA
FRANKLIN LAKES, NJ 07417-1880

BECTON DICKINSON & CO. 510(k) NO: K012351 DEVICE: BDPROBETEC ET CT/GC AMPLIFIED DNA ASSAY
ATTN: COLLEEN A ROHREECK PHONE NO : 410-316-4988 SE DECISION MADE: 18-SEP-2001
7 LOVETON CIR. 510(k) SUMMARY AVAILABLE FROM FDA
SPARKS, MD 21152-0999

BECTON DICKINSON AND CO. 510(k) NO: K010572 DEVICE: BD VISIDRAPE OPHTHALMIC DRAPES; BD VISIFLEX INCISE DRAPE
ATTN: JAMES STAFFIERA PHONE NO : 941-359-7013 SE DECISION MADE: 12-MAR-2001
7575 COMMERCE COURT 510(k) STATEMENT
SARASOTA, FL 34243-3212

BECTON DICKINSON AND CO. 510(k) NO: K010890 DEVICE: BD ULTRA-FINE II INSULIN SYRINGE-MINI NEEDLE, MODEL 30G * 3/16
(5MM)
ATTN: PETER ZURLO PHONE NO : 201-847-6447 SE DECISION MADE: 19-APR-2001
1 BECTON DRIVE 510(k) SUMMARY AVAILABLE FROM FDA
FRANKLIN LAKES, NJ 07417-1880

BECTON DICKINSON BIOSCIENCES 510(k) NO: K000884 DEVICE: BD PROBETEC ET MYCOBACTERIUM TUBERCULOSIS COMPLEX (CTB) CULTUR
E IDENTIFICATION ASSAY
ATTN: COLLEEN ROHREECK PHONE NO : 410-316-4988 SE DECISION MADE: 19-JAN-2001
7 LOVETON CIRCLE 510(k) SUMMARY AVAILABLE FROM FDA
SPARKS, MD 21152

BECTON DICKINSON INFUSION THERAPY 510(k) NO: K013073 DEVICE: INSYTE, ANGIOCATH, INSYTE AUTOGUARD, ANGIOCATH AUTOGUARD, AUTO
GUARD PRO, INTIMA AND SAF-T-INTIMA INTRAVASCULAR CATHETERS
ATTN: LESLIE WOOD PHONE NO : 801-565-2504 SE DECISION MADE: 08-NOV-2001
9450 SOUTH STATE ST. 510(k) SUMMARY AVAILABLE FROM FDA
SANDY, UT 84070

BECTON DICKINSON INFUSION THERAPY 510(k) NO: K013800 DEVICE: INSYTE, ANGIOCATH, INSYTE AUTOGUARD, ANGIOCATH AUTOGUARD, AUTO
GUARD PRO, INTIMA, AND SAF-T-INTIMA INTRAVASCULAR CATHETE
ATTN: LESLIE WOOD PHONE NO : 801-565-2504 SE DECISION MADE: 21-DEC-2001
9450 SOUTH STATE ST. 510(k) SUMMARY AVAILABLE FROM FDA
SANDY, UT 84070

BEHIVE LTD 510(k) NO: K012746 DEVICE: ICE BATON
ATTN: MARY MCNAMARA-CULLINANE PHONE NO : 508-643-0434 SE DECISION MADE: 14-NOV-2001
49 PLAIN STREET 510(k) SUMMARY AVAILABLE FROM FDA
NORTH ATTLEBORO, MA 02760

BEIJING REAGENT LATEX PRODUCTS 510(k) NO: K010947 DEVICE: SNOW LOTUS POWDER FREE LATEX EXAMINATION GLOVES WITH A PROTEIN
CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)
ATTN: CHRISTINA SMITH PHONE NO : 410-451-0639 SE DECISION MADE: 25-MAY-2001
PO BOX 4341 510(k) STATEMENT
CROFTON, MD 21114

BEIJING REAGENT LATEX PRODUCTS 510(k) NO: K012104 DEVICE: "SNOW LOTUS" POWDER-FREE LATEX SURGEON'S GLOVES
ATTN: WANG YANNAN PHONE NO : 86 10 81502573 SE DECISION MADE: 21-AUG-2001
NO. 30 SOUTH SANLITUN ROAD,
DONGDAQIAO 510(k) SUMMARY AVAILABLE FROM FDA
CHAOWAI, BEIJING, P.R.,

BELL DENTAL PRODUCTS, LLC. 510(k) NO: K011222 DEVICE: PORTABELL, MODEL 4200
ATTN: DAN BELL PHONE NO : 303-292-2137 SE DECISION MADE: 25-JUN-2001
3003 ARAPAHOE ST., #101-B 510(k) STATEMENT
DENVER, CO 80205

BENLAN, INC. 510(k) NO: K010607 DEVICE: MED-RX IRRIGATION SET, MODEL 10-3001, 10-3002, 10-4000, 10-400
1
ATTN: BILL LIM PHONE NO : 905 829 5004 SE DECISION MADE: 28-NOV-2001
2760 BRIGHTON RD. 510(k) SUMMARY AVAILABLE FROM FDA
OAKVILLE, ONTARIO,

BENTEC MEDICAL, INC. 510(k) NO: K002650 DEVICE: VAN ANDLE DILATION, EMERALD GUIDEWIRE, MODEL VAD6, 502-726
ATTN: DAVID TUCKER PHONE NO : 530-406-3333 SE DECISION MADE: 16-FEB-2001
1380 EAST BEAMER ST. 510(k) SUMMARY AVAILABLE FROM FDA
WOODLAND, CA 95776

BENZ RESEARCH AND DEVELOPMENT CORP510(k) NO: K003861 DEVICE: BENZ-MF (VISIBILITY HANGLING TINT) (METHAFILCON A) SOFT DAILY
WEAR CONTACT LENS (LATHE-CUT)
ATTN: MARTIN DALSING PHONE NO : 970-243-5490 SE DECISION MADE: 08-MAR-2001
623 GLACIER DRIVE 510(k) SUMMARY AVAILABLE FROM FDA
GRAND JUNCTION, CO 81503

BESCON CO., LTD. 510(k) NO: K001962 DEVICE: S45 (OCUFILCON A) SPHERICAL, ASPHERICAL, TORIC AND MULTIFOCAL
SOFT CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED, FULLY-
ATTN: MARTIN DALSING PHONE NO : 970-243-5490 SE DECISION MADE: 09-JUL-2001
623 GLACIER DRIVE 510(k) SUMMARY AVAILABLE FROM FDA
GRAND JUNCTION, CO 81503

BESCON CO., LTD. 510(k) NO: K002099 DEVICE: S38 (POLYMACON) SPHERICAL, ASPHERICAL, TORIC AND MULTIFOCAL SC
FT CONTACT LENS FOR DAILY WEAR(CLEAR AND TINTED, FULLY-
ATTN: MARTIN DALSING PHONE NO : 970-243-5490 SE DECISION MADE: 09-JUL-2001
623 GLACIER DRIVE 510(k) SUMMARY AVAILABLE FROM FDA
GRAND JUNCTION, CO 81503

BEST MANUFACTURING COMPANY 510(k) NO: K012166 DEVICE: NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE (BROWN)
ATTN: DAVID C YOUNG PHONE NO : 706-862-2302 SE DECISION MADE: 01-AUG-2001
579 EDISON STREET 510(k) SUMMARY AVAILABLE FROM FDA
MENLO, GA 30731

BEST MANUFACTURING COMPANY 510(k) NO: K012899 DEVICE: GREEN NITRILE POWDER-FREE MEDICAL EXMAINATION GLOVE
ATTN: DAVID C YOUNG PHONE NO : 706-862-2302 SE DECISION MADE: 18-SEP-2001
579 EDISON STREET 510(k) STATEMENT
MENLO, GA 30731

BETA BIOMED SERVICES, INC.
ATTN: EJ SMITH
P.O. BOX 4341
CROFTON, MD 21114
510(k) NO: K003542
PHONE NO : 410-451-0639
DEVICE: PREAMP CABLE, MODEL B400-1011PA
SE DECISION MADE: 06-APR-2001
510(k) STATEMENT

BHS INTL., INC.
ATTN: CHRIS REDDING
2431 CROFTON LN., SUITE 9
CROFTON, MD 21114
510(k) NO: K000814
PHONE NO : 410-721-5055
DEVICE: FINGER PULSE METER
SE DECISION MADE: 29-MAR-2001
510(k) STATEMENT

BINAX, INC.
IGEN TEST
ATTN: PAMELA S ANGELL
217 READ ST.
PORTLAND, ME 04103
510(k) NO: K010523
PHONE NO : 207-772-3988
DEVICE: MODIFICATION TO BINAX NOW STREPTOCOCCUS PNEUMONIAE URINARY ANI
SE DECISION MADE: 15-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BINAX, INC.
ATTN: PAMELA ANGELL
217 READ ST.
PORTLAND, ME 04103
510(k) NO: K012521
PHONE NO : 207-772-3988
DEVICE: BINAX NOW STREPTOCOCCUS PNEUMONIAE TEST
SE DECISION MADE: 30-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

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-LOGIC SYSTEMS CORP.
ATTN: NORMAN E BRUNNER
ONE BIO-LOGIC PLAZA
MUNDELEIN, IL 60060-3700
510(k) NO: K012384
PHONE NO : 847-949-5200
DEVICE: EAR MUFFINS
SE DECISION MADE: 15-OCT-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: SLENDERTONE FLEX, MODEL, 512
SE DECISION MADE: 27-SEP-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIO-PLEXUS, INC.
ATTN: PAUL A TENTHOREY
129 RESERVOIR RD.
VERNON, CT 06066-5705
510(k) NO: K003827
PHONE NO : 860-870-6112
DEVICE: PUNCTUR-GUARD WINGED SET FOR BLOOD COLLECTION
SE DECISION MADE: 08-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES
NOLOGY CONTROL LEVEL 1, 3 ML, LIQUICHEK IMMUNOLOGY CONTROL
ATTN: DONNA CHAPMAN
9500 JERONIMO RD.
IRVINE, CA 92618-2017
510(k) NO: K011494
PHONE NO : 949-598-1200
DEVICE: LIQUICHEK IMMUNOLOGY CONTROL LEVEL 1,2,3,1, ML, LIQUICHEK IMMU
SE DECISION MADE: 08-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES
ATTN: YVETTE LLOYD
9500 JERONIMO RD.
IRVINE, CA 92618-2017

510(k) NO: K011579
PHONE NO : 949-598-1465

DEVICE: LYPHOCHEK TUMOR MARKER CONTROL, LEVELS 1 AND 2, 2ML, MODEL 580
SE DECISION MADE: 26-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES
6E21-10
ATTN: DONNA CHAPMAN
9500 JERONIMO RD.
IRVINE, CA 92618-2017

510(k) NO: K011853
PHONE NO : 949-598-1200

DEVICE: ABBOTT TUMORMARKER-MCC (LYOPHILIZED), LEVELS 1 AND 2, 2ML NO.
SE DECISION MADE: 17-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES
00; LEVEL 3 #981800
ATTN: DONNA CHAPMAN
9500 JERONIMO ROAD
IRVINE, CA 92618

510(k) NO: K011867
PHONE NO : 949-598-1200

DEVICE: LIQUID ASSAYED MULTIQUAL CONTROL LEVEL1 #981600; LEVEL 2 #9817
SE DECISION MADE: 12-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012513
PHONE NO : 949-598-1367

DEVICE: LIQUICHEK LIPIDS CONTROL LEVEL 1, LIQUICHEK LIPIDS CONTROL LEV
SE DECISION MADE: 29-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

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 L
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

BIO-RESEARCH ASSOCIATES, INC.
ATTN: JOHN C RADKE
4113 NORTH PORT WASHINGTON RD.
MILWAUKEE, WI 53212

510(k) NO: K003176
PHONE NO : 414-332-3003

DEVICE: BIOEMG II AND BIOJVA
SE DECISION MADE: 04-JAN-2001
510(k) STATEMENT

BIO-SCAN, INC. ATTN: BUTCH SMITH 6 WALDEN ROAD CORRALES, NM 87048	510(k) NO: K003480 PHONE NO : 505-867-9854	DEVICE: BIOFIND SE DECISION MADE: 11-MAY-2001 510(k) STATEMENT
BIOCARE CORP. FOR URINALYSIS ATTN: BRUCE A MACFARLAND 5182 WEST 76TH STREET MINNEAPOLIS, MN 55439	510(k) NO: K012829 PHONE NO : 952-646-3188	DEVICE: STRIPMAX 1210 URINE CHEMISTRY ANALYZER, URIMATE REAGENT STRIP SE DECISION MADE: 02-NOV-2001 510(k) STATEMENT
BIOCHECK, INC. Y TEST KIT, MODEL BC-1119 ATTN: ROBIN J HELLEN 9418 LASAINE AVE NORTHRIDGE, CA 91325	510(k) NO: K003851 PHONE NO : 818-709-5646	DEVICE: BIOCHECK HIGH SENSITIVITY C-REACTIVE PROTEIN ENZYME IMMUNOASSA SE DECISION MADE: 20-JUL-2001 510(k) STATEMENT
BIOCOMPOSITES LTD. ATTN: J.STEPHEN BRATT ETRUSCAN ST., ETRURIA STOKE ON TRENT,	510(k) NO: K003641 PHONE NO : 441 782 206500	DEVICE: BIOLOK SCREW, BIOSTEON SCREW SE DECISION MADE: 08-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOCOMPOSITES LTD. ATTN: J. STEPHEN BRATT ETRUSCAN STREET ETRURIA STOKE ON TRENT, STAFFORDSHIRE,	510(k) NO: K003954 PHONE NO : 441 782 206500	DEVICE: STIMULAN - CALCIUM SULFATE BONE VOID FILLER KIT SE DECISION MADE: 12-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOCORE MEDICAL TECHNOLOGIES, INC. ATTN: AJAY KUMAR 11800 TECH ROAD, SUITE # 240 SILVER SPRING, MD 20904-1908	510(k) NO: K012990 PHONE NO : 301-625-6818	DEVICE: COLLATEK POWDER SE DECISION MADE: 24-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOCORE MEDICAL TECHNOLOGIES, INC. ATTN: AJAY KUMAR 11800 TECH ROAD, SUITE # 240 SILVER SPRING, MD 20904-1908	510(k) NO: K012995 PHONE NO : 301-625-6818	DEVICE: COLLATEK SHEET SE DECISION MADE: 25-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOCORE MEDICAL TECHNOLOGIES, INC. ATTN: AJAY KUMAR 11800 TECH ROAD, SUITE # 240 SILVER SPRING, MD 20904-1908	510(k) NO: K012997 PHONE NO : 301-625-6818	DEVICE: COLLATEK FOAM SE DECISION MADE: 25-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIODERMIS CORP. ATTN: JEFF S SCHLEUING 3078 EAST SUNSET RD. SUITE #1 LAS VEGAS, NV 89120	510(k) NO: K003948 PHONE NO : 800-322-3729	DEVICE: EPI-DERM SILICONE GEL SHEETING SE DECISION MADE: 29-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOENTERICS CORP. ATTN: DAVID MUNJAL 1035 CINDY LN. CARPINTERIA, CA 93013	510(k) NO: K002838 PHONE NO : 805-684-3045	DEVICE: GASTRIC SUCTION AND DRAINAGE CATHETER SE DECISION MADE: 09-JUL-2001 510(k) STATEMENT
BIOFILM, INC. JELLY (OTC CONSUMER MARKET) ATTN: ROBERT L DE ARMOND 3121 SCOTT ST. VISTA, CA 92083	510(k) NO: K003867 PHONE NO : 760-727-9030	DEVICE: EXAM ROOM ASTROGLIDE (PROFESSIONAL MARKET), TARGET LUBRICATING SE DECISION MADE: 09-MAR-2001 510(k) STATEMENT
BIOFORM, INC. ATTN: VICTOR M BOWERS 4133 COURTNEY ROAD, #10 FRANKSVILLE, WI 53126	510(k) NO: K012955 PHONE NO : 262-835-9800	DEVICE: COAPTITE TISSUE MARKER AND COAPTITE FN TISSUE MARKER SE DECISION MADE: 22-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOHORIZONS IMPLANT SYSTEMS, INC. ATTN: STEVEN BOGGAN ONE PERIMETER PARK SOUTH SUITE 230, SOUTH BIRMINGHAM, AL 35243	510(k) NO: K010458 PHONE NO : 205-967-7880	DEVICE: THE MAESTRO SYSTEM SE DECISION MADE: 10-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOHORIZONS IMPLANT SYSTEMS, INC. ATTN: DONALD E DALTON ONE PERIMETER PARK SOUTH SUITE 230, SOUTH BIRMINGHAM, AL 35243	510(k) NO: K011675 PHONE NO : 205-967-7880	DEVICE: THE AUTOTAC SYSTEM SE DECISION MADE: 22-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOJECT, INC. ATTN: NANCY J GERTLAR 7620 S.W. BRIDGEPORT RD. PORTLAND, OR 97224	510(k) NO: K003908 PHONE NO : 800-683-7221	DEVICE: SEROJET SE DECISION MADE: 08-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOJECT, INC. ATTN: NANCY GERTLAR 7620 S.W. BRIDGEPORT RD. PORTLAND, OR 97224	510(k) NO: K010623 PHONE NO : 800-683-7221	DEVICE: RECONSTITUTION KIT & VIAL CONNECTOR SE DECISION MADE: 05-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOLASE TECHNOLOGY, INC. ATTN: IOANA M RIZOIU 981 CALLE AMANECER SAN CLEMENTE, CA 92673	510(k) NO: K003385 PHONE NO : 949-361-1200	DEVICE: TWILITE, TWILITE WHITE SE DECISION MADE: 25-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOLASE TECHNOLOGY, INC. 510(k) NO: K011041 DEVICE: WATERLASE, MILLENNIUM
ATTN: IOANA M RIZOIU PHONE NO : 949-361-0204 SE DECISION MADE: 03-JUL-2001
981 CALLE AMANECER 510(k) SUMMARY AVAILABLE FROM FDA
SAN CLEMENTE, CA 92673

BIOLITEC, INC. 510(k) NO: K010689 DEVICE: MEGABEAM/CERALAS NON STERILE FIBER OPTIC LASER DELIVERY SYSTEM
S, MODEL 200,320,400 OR 600UM
ATTN: CAROL J MORELLO PHONE NO : 413-525-0600 SE DECISION MADE: 18-MAY-2001
515 SHAKER ROAD 510(k) SUMMARY AVAILABLE FROM FDA
EAST LONGMEADOW, MA 01028

BIOLITEC, INC. 510(k) NO: K010804 DEVICE: MEGABEAM/CERALAS REUSEABLE HANDPIECE AND DISPOSABLE TIPS
ATTN: CAROL J MORELLO PHONE NO : 413-525-0600 SE DECISION MADE: 04-OCT-2001
515 SHAKER ROAD 510(k) SUMMARY AVAILABLE FROM FDA
EAST LONGMEADOW, MA 01028

BIOLITEC, INC. 510(k) NO: K013193 DEVICE: MEGA BEAM/CERALAS NONSTERILE COLLIMATING HANDPIECE
ATTN: CAROL J MORELLO PHONE NO : 413-525-0600 SE DECISION MADE: 21-DEC-2001
515 SHAKER ROAD 510(k) SUMMARY AVAILABLE FROM FDA
EAST LONGMEADOW, MA 01028

BIOLUCENT, INC. 510(k) NO: K003795 DEVICE: BIOLUCENT MAMMOGRAPHY CUSHION
ATTN: STEVE GEX PHONE NO : 949-349-1380 SE DECISION MADE: 14-FEB-2001
27121 ALISO CREEK ROAD
SUITE 125 510(k) SUMMARY AVAILABLE FROM FDA
ALISO VIEJO, CA 92656

BIOMEDICAL ENT., INC. 510(k) NO: K001353 DEVICE: MEMOGRAPH; OSSTAPLE - NEUROSURGICAL USES FOR CRANIOFACIAL FRAC
TURES AND CRANIOPLASTY FOR THE MEMOGRAPH STAPLE SYSTEM
ATTN: W. CASEY FOX PHONE NO : 210-677-0354 SE DECISION MADE: 13-MAR-2001
14785 OMICRON DR., SUITE 205 510(k) SUMMARY AVAILABLE FROM FDA
SAN ANTONIO, TX 78245

BIOMEDICAL ENT., INC. 510(k) NO: K001354 DEVICE: MEMOGRAPH; OSSTAPLE - ORTHOPEDIC USES FOR SMALL BONE AND FRAGM
ENT FIXATION FOR THE MEMOGRAPH STAPLE SYSTEM
ATTN: W. CASEY FOX PHONE NO : 210-677-0354 SE DECISION MADE: 13-MAR-2001
14785 OMICRON DR., SUITE 205 510(k) SUMMARY AVAILABLE FROM FDA
SAN ANTONIO, TX 78245

BIOMEDICAL LIFE SYSTEMS, INC. 510(k) NO: K010209 DEVICE: ELECTRO-NERVE STIMULATOR TENS, MODEL HE-DIGITAL
ATTN: RICHARD SAXON PHONE NO : 760-727-5600 SE DECISION MADE: 12-JUN-2001
P.O. BOX 1360 510(k) STATEMENT
VISTA, CA 92085-1360

BIOMEDICAL LIFE SYSTEMS, INC. 510(k) NO: K010749 DEVICE: ELECTRO NEUROMUSCULAR STIMULATOR, MODEL "NMS-DIGITAL"
ATTN: RICHARD SAXON PHONE NO : 760-727-5600 SE DECISION MADE: 28-SEP-2001
P.O. BOX 1360 510(k) STATEMENT
VISTA, CA 92085-1360

BIOMERICA, INC. ATTN: JAY SINGH 1533 MONROVIA AVE. NEWPORT BEACH, CA 92663	510(k) NO: K003856 PHONE NO : 949-645-2111	DEVICE: EZ-HCG URINE(PREGNANCY TEST) SE DECISION MADE: 21-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMERIEUX, INC. ATTN: NANCY WEAVER 595 ANGLUM RD. HAZELWOOD, MO 63042	510(k) NO: K010550 PHONE NO : 314-731-8695	DEVICE: VIDAS TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA), MODEL 30 428 SE DECISION MADE: 24-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
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 AVAILABLE FROM FDA
BIOMET MANUFACTURING, INC. ATTN: SARA A BAILEY AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K010664 PHONE NO : 219-372-1568	DEVICE: COPELAND RESURFACING HUMERAL HEADS SE DECISION MADE: 05-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET MANUFACTURING, INC. ATTN: SARA B SHULTZ P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K012469 PHONE NO : 219-267-6639	DEVICE: RESORBABLE NO PROFILE SCREW AND WASHER SE DECISION MADE: 03-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET MANUFACTURING, INC. ATTN: SARA B SHULTZ 56 EAST BELL DRIVE P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K012503 PHONE NO : 219-267-6639	DEVICE: METAL SCREW ANCHOR SE DECISION MADE: 22-OCT-2001 510(k) SUMMARY AVAILABLE 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
BIOMET ORTHOPEDICS, , INC. ATTN: SARA B SHULTZ P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K013042 PHONE NO : 219-267-6639	DEVICE: DISCOVERY ELBOW SE DECISION MADE: 10-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET ORTHOPEDICS, , INC. ATTN: SARA B SHULTZ P.O. BOX 587 WARSAW, IN 46582	510(k) NO: K013534 PHONE NO : 219-267-6639	DEVICE: SELF-COUNTERSINKING BONE SCREW SE DECISION MADE: 17-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOMET ORTHOPEDICS, , INC. ATTN: TRACY J BICKEL P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K013657 PHONE NO : 219-267-6639	DEVICE: MODIFICATION TO: BIOMET HUMERAL CABLE PLATES SE DECISION MADE: 03-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MARY VERSTYNEN AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K993836 PHONE NO : 219-267-6639	DEVICE: GENERATION 4 BONE CEMENT SE DECISION MADE: 19-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: CAROL LAUSTER 56 EAST BELL DRIVE PO BOX 587 WARSAW, IN 46581-0587	510(k) NO: K001581 PHONE NO : 219-372-1913	DEVICE: LACTOSORB 5.0 MM WASHER SE DECISION MADE: 20-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: SARA A BAILEY AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K003253 PHONE NO : 219-372-1568	DEVICE: BIOMET'S MINIMALLY CONSTRAINED ELBOW SE DECISION MADE: 12-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MARY VERSTYNEN AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K003273 PHONE NO : 219-267-6639	DEVICE: LACTOSORB SCREW ANCHOR SE DECISION MADE: 11-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: CAROL LAUSTER AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K003281 PHONE NO : 219-372-1913	DEVICE: LACTOSORB RAPIDFLAP SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: SARA A BAILEY AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K003493 PHONE NO : 219-372-1568	DEVICE: 3I CALCIUM SODIUM PHOSPHATE BONE CEMENT SE DECISION MADE: 09-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MICHELLE L MCKINLEY AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K003494 PHONE NO : 219-267-6639	DEVICE: MIMIX BONE REPLACEMENT SYSTEM SE DECISION MADE: 09-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC. ATTN: DALENE T BINKLEY 56 EAST BELL DRIVE WARSAW, IN 46581-0587	510(k) NO: K010027 PHONE NO : 800-348-9500	DEVICE: MAXIM KNEE SYSTEM SE DECISION MADE: 12-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: CAROL LAUSTER AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K010212 PHONE NO : 219-267-6639	DEVICE: OFFSET TIBIAL TRAY SE DECISION MADE: 14-FEB-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: LONNIE WITHAM 56 EAST BELL DRIVE WARSAW, IN 46581-0587	510(k) NO: K010348 PHONE NO : 219-372-1510	DEVICE: TANTALUM BEADS - RADIOGRAPHIC MARKER SE DECISION MADE: 03-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MICHELLE L MCKINLEY P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K010560 PHONE NO : 219-372-1644	DEVICE: PORTRAIT FEMORAL COMPONENT SE DECISION MADE: 20-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MARY L VERSTYNEN AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K010635 PHONE NO : 219-267-6639	DEVICE: INTERLOK / HA COPELAND RESURFACING HEADS SE DECISION MADE: 20-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MICHELLE L MCKINLEY 56 EAST BELL P.O. BOX 587 WARSAW, IN 46582	510(k) NO: K010774 PHONE NO : 219-372-1644	DEVICE: AVL HINGE KNEE SYSTEM SE DECISION MADE: 13-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MICHELLE L MCKINLEY P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011110 PHONE NO : 219-267-6639	DEVICE: M2A ACETABULAR SYSTEM SE DECISION MADE: 02-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: SARA A BAILEY P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011137 PHONE NO : 219-372-1568	DEVICE: RESORBABLE HAMMERTOE PIN SE DECISION MADE: 19-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: PATRICIA S BERES P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011138 PHONE NO : 219-267-6639	DEVICE: OXFORD UNICOMPARTMENTAL KNEE FEMORAL COMPONENT SE DECISION MADE: 10-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC. ATTN: TRACY J BICKEL AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011139 PHONE NO : 219-372-1761	DEVICE: LORENZ LACTOSORB PANELS AND FASTENERS SE DECISION MADE: 20-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: DALENE T BINKLEY 56 EAST BELL DRIVE WARSAW, IN 46581-0587	510(k) NO: K011219 PHONE NO : 219-267-6639	DEVICE: ASCENT KNEE SYSTEM SE DECISION MADE: 18-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: DALENE T BINKLEY P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011237 PHONE NO : 219-372-1612	DEVICE: LACTOSORB PLATES, MESHES, AND PANELS/SHEETS SE DECISION MADE: 23-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: SARA BAILEY SHULTZ P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011451 PHONE NO : 219-372-1568	DEVICE: REUNITE FUSION SCREW SE DECISION MADE: 10-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: TRACY J BICKEL AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011455 PHONE NO : 219-267-6639	DEVICE: BIOMET ONCOLOGY SALVAGE SYSTEM (OSS) TAPER STACKING ADAPTER SE DECISION MADE: 18-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: TRACY J BICKEL 56 EAST BELL DRIVE WARSAW, IN 46581-0587	510(k) NO: K011509 PHONE NO : 219-267-6639	DEVICE: BARRETT UNICONDYLAR TIBIAL BEARING SE DECISION MADE: 13-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MARY L VERSTYNEN AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K011522 PHONE NO : 219-267-6639	DEVICE: RESORBABLE BONE PINS SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: PATRICIA SANDBORN BERES P.O. BOX 587 WARSAW, IN 46581	510(k) NO: K011554 PHONE NO : 219-267-6639	DEVICE: LORENZ LACTOSORB VOCAL MEDIALIZATION IMPLANT SE DECISION MADE: 26-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: TRACY J BICKEL 56 EAST BELL DRIVE WARSAW, IN 46581-0587	510(k) NO: K011795 PHONE NO : 219-267-6639	DEVICE: WORLAND UNICONDYLAR TIBIAL BEARING SE DECISION MADE: 13-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC. ATTN: DALENE T BINKLEY 56 EAST BELL DRIVE WARSAW, IN 46582-0587	510(k) NO: K012019 PHONE NO : 219-267-6639	DEVICE: COLOR BUFFED (CB) DDH FEMORAL STEM SE DECISION MADE: 20-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: MICHELLE MCKINLEY P.O. BOX 587 WARSAW, IN 46581	510(k) NO: K012348 PHONE NO : 219-267-6639	DEVICE: MAXIM RPG PS FEMORAL COMPONENT SE DECISION MADE: 15-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: SARA B SHULTZ 56 EAST BELL DRIVE PO BOX 587 WARSAW, IN 46582	510(k) NO: K012569 PHONE NO : 219-267-6639	DEVICE: MODIFICATION TO: INJECTABLE MIMIX SE DECISION MADE: 21-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: SARA B SHULTZ 56 EAST BELL DRIVE PO BOX 587 WARSAW, IN 46581-0578	510(k) NO: K012572 PHONE NO : 219-267-6639	DEVICE: SOFT TISSUE SCREW AND WASHER SE DECISION MADE: 03-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: DALENE T BINKLEY P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K012798 PHONE NO : 800-348-9500	DEVICE: INTEX SCREW SE DECISION MADE: 16-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOMETRIX LTD. ATTN: MIRIAM ABUTBUL 4 KIRYAT MADA, P.O. BOX 45057 JERUSALEM,	510(k) NO: K011216 PHONE NO : 972 2 5861241	DEVICE: PVC FREE INTRAVASCULAR ADMINISTRATION SET SE DECISION MADE: 18-JUL-2001 510(k) STATEMENT
BION DIAGNOSTIC SCIENCES ATTN: HELEN LANDICHO 12277 134TH CT., N.E., #100 REDMOND, WA 98052	510(k) NO: K012559 PHONE NO : 425-814-1514	DEVICE: POLY STAT HCG TEST SE DECISION MADE: 16-OCT-2001 510(k) STATEMENT
BIONET COMPANY LTD ATTN: MIN SOO HAN 3F, DAEYANG BLDG., 999 DAECHI-DONG, KANGNAM-GU SEOUL,	510(k) NO: K011328 PHONE NO : 822 346 83660	DEVICE: CARDIO CARE EKG-2000 12-CHANNEL ELECTROCARDIOGRAPH SE DECISION MADE: 21-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIONOSTICS, INC. NA GL3 ATTN: KATHY STORRO 2 CRAIG RD. ACTON, MA 01720	510(k) NO: K012430 PHONE NO : 978-263-3856	DEVICE: MULTI-METER GLUCOSE CALIBRATION VERIFICATION MATERIAL, MODEL R SE DECISION MADE: 27-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIONOSTICS, INC. 510(k) NO: K012431 DEVICE: COMBITROL TS MULTI ANALYTE CONTROL, LEVELS 1,2,3, AUTOTROL TS
MULTI ANALYTE CONTROL, LEVELS 1,2,3
ATTN: KATHY STORRO PHONE NO : 978-263-3856 SE DECISION MADE: 28-AUG-2001
2 CRAIG RD. 510(k) SUMMARY AVAILABLE FROM FDA
ACTON, MA 01720

BIONOSTICS, INC. 510(k) NO: K013147 DEVICE: GLUCOSE CONTROL SOLUTION FOR THERASENSE FREESTYLE
ATTN: KATHY STORRO PHONE NO : 978-772-7070 SE DECISION MADE: 24-OCT-2001
7 JACKSON ROAD 510(k) SUMMARY AVAILABLE FROM FDA
DEVENS, MA 01432

BIONX IMPLANTS, INC. 510(k) NO: K003659 DEVICE: PLGA PIN, MODEL 171120,171140,171520,171540,171560,172020,1720
40,172060,173240,173260
ATTN: TUIJA ANNALA PHONE NO : 358 331 65600 SE DECISION MADE: 20-FEB-2001
HERMIANKATU 6-8 L 510(k) SUMMARY AVAILABLE FROM FDA
TAMPERE,

BIONX IMPLANTS, INC. 510(k) NO: K003756 DEVICE: BIOSORBFX TACK AND BIOSORBPDX TACK BIOABSORBABLE FIXATION FAST
ENER, USED WITH PLATES
ATTN: DAVID W ANDERSON PHONE NO : 215-643-5000 SE DECISION MADE: 03-JAN-2001
1777 SENTRY PKWY. WEST,
GWYNEDD HALL, SUITE 400 510(k) SUMMARY AVAILABLE FROM FDA
BLUE BELL, PA 19422

BIONX IMPLANTS, INC. 510(k) NO: K003970 DEVICE: CONTOUR LABRAL NAIL, MODEL 533520A
ATTN: TUIJA ANNALA PHONE NO : 358 331 65600 SE DECISION MADE: 12-JAN-2001
HERMIANKATU 6-8 L 510(k) SUMMARY AVAILABLE FROM FDA
TAMPERE,

BIONX IMPLANTS, INC. 510(k) NO: K010554 DEVICE: MENISCUS ARROW SHEATH #CN1000A; SMARTSCREW ACL SHEATH #SSA2000
A
ATTN: TUIJA ANNALA PHONE NO : 358 331 65600 SE DECISION MADE: 25-MAY-2001
HERMIANKATU 6-8 L 510(k) SUMMARY AVAILABLE FROM FDA
TAMPERE,

BIONX IMPLANTS, INC. 510(k) NO: K010687 DEVICE: BIOSORBFX AND BIOSORBPDX MESH
ATTN: TUIJA ANNALA PHONE NO : 358 331 65600 SE DECISION MADE: 14-MAR-2001
HERMIANKATU 6-8 L 510(k) SUMMARY AVAILABLE FROM FDA
TAMPERE,

BIONX IMPLANTS, INC. 510(k) NO: K010983 DEVICE: PLLA PIN
ATTN: TUIJA ANNALA PHONE NO : 358 3 3165679 SE DECISION MADE: 13-JUN-2001
HERMIANKATU 6-8 L 510(k) SUMMARY AVAILABLE FROM FDA
TAMPERE,

BIONX IMPLANTS, INC. 510(k) NO: K012334 DEVICE: CONTOUR MENISCUS ARROW, MODELS 541110, 541113, AND 541116
ATTN: TUIJA ANNALA PHONE NO : 358 3 3165600 SE DECISION MADE: 19-SEP-2001
HERMIANKATU 6-8 L 510(k) SUMMARY AVAILABLE FROM FDA
TAMPERE,

BIONX IMPLANTS, INC. ATTN: TUIJA ANNALA HERMIANKATU 6-8 L TAMPERE,	510(k) NO: K013057 PHONE NO : 358 331 65600	DEVICE: BIOCUFF,C, MODELS 236018, 236028, 236036 SE DECISION MADE: 12-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIONX IMPLANTS, INC. 4 ATTN: TUIJA ANNALA HERMIANKATU 6-8 L TAMPERE,	510(k) NO: K013546 PHONE NO : 358 331 65600	DEVICE: MODIFICATION TO: 1.5 BONE FIXATION KIT, MODELS BXS6114, BXS621 SE DECISION MADE: 21-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIONX IMPLANTS, LTD. ATTN: GERARD S CARLOZZI 1777 SENTRY PARKWAY WEST BLUEBELL, PA 19422	510(k) NO: K003077 PHONE NO : 215-643-5000	DEVICE: SMARTSCREW MODEL 222006...227510 SE DECISION MADE: 26-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIONX IMPLANTS, LTD. ATTN: TUIJA 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
BIONX IMPLANTS, LTD. ATTN: TUIJA ANNALA P.O. BOX 3 HERMIANKATU 6-8L TAMPERE,	510(k) NO: K012000 PHONE NO : 358 331 65600	DEVICE: 1.5MM BONE FIXATION KIT SE DECISION MADE: 18-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIONX IMPLANTS, LTD. ATTN: TUIJA ANNALA P.O. BOX 3 HERMIANKATU 6-8L TAMPERE,	510(k) NO: K012001 PHONE NO : 358 331 65600	DEVICE: SMARTSCREW SE DECISION MADE: 18-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPLATE, INC. ACIAL SURGERY, BIOLACTATE ATTN: ERIC V HOHENSTEIN 6911 MELROSE AVENUE LOS ANGELES, CA 90038	510(k) NO: K994060 PHONE NO : 323-549-9500	DEVICE: THE BIOPLATE RESORBABLE BONE PLATING SYSTEM FOR CRANIOMAXILLOF SE DECISION MADE: 24-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPLATE, INC. LOFACIAL SURGERY ATTN: CAROL E JONES 6911 MELROSE AVE. LOS ANGELES, CA 90038	510(k) NO: K002426 PHONE NO : 323-549-9500	DEVICE: THE BIOPLATE REGID FIXATION BONE PLATING SYSTEM FOR CRANOMAXIL SE DECISION MADE: 26-JAN-2001 510(k) STATEMENT
BIOPLATE, INC. M ATTN: CAROL E JONES 6911 MELROSE AVE. LOS ANGELES, CA 90038	510(k) NO: K011380 PHONE NO : 323-549-9500	DEVICE: MODIFICATION TO THE BIOPLATE BIOCLIP CRANIOTOMY FIXATION SYSTE SE DECISION MADE: 14-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOPLATE, INC. ATTN: ERIC V HOHENSTEIN 6911 MELROSE AVE. LOS ANGELES, CA 90038	510(k) NO: K012908 PHONE NO : 323-549-9500	DEVICE: BIOPLATE RESORBABLE BONE SCREW SE DECISION MADE: 28-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPLATE, INC. ATTN: BRUCE F MACKLER 1666 K STREET NW SUITE 200 WASHINGTON, DC 20006-4004	510(k) NO: K012910 PHONE NO : 202-912-2000	DEVICE: THE BIOPLATE MANDIBLE FIXATION SYSTEM SE DECISION MADE: 20-NOV-2001 510(k) STATEMENT
BIOPLATE, INC. ATTN: CAROL E JONES 6911 MELROSE AVE. LOS ANGELES, CA 90038	510(k) NO: K013050 PHONE NO : 323-549-9500	DEVICE: THE BIOPLATE ZIP CRANIOTOMY FIXATION SYSTEM SE DECISION MADE: 10-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPLATE, INC. ATTN: CAROL E JONES 6911 MELROSE AVE. LOS ANGELES, CA 90038	510(k) NO: K013055 PHONE NO : 323-549-9500	DEVICE: THE BIOPLATE BIOCLIP CRANIOTOMY FIXATION SYSTEM SE DECISION MADE: 07-DEC-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
BIOPRO, INC. ATTN: ANGENA PAREKH 17 SEVENTEENTH ST. PORT HURON, MI 48060	510(k) NO: K010149 PHONE NO : 810-982-7777	DEVICE: WUJIN #3 FEMORAL NAIL SE DECISION MADE: 17-APR-2001 510(k) STATEMENT
BIOPRO, INC. ATTN: PATRICK PRINGLE 17 SEVENTEENTH ST. PORT HURON, MI 48060	510(k) NO: K011459 PHONE NO : 810-982-7777	DEVICE: WUJIN #3 FEMORAL BONE PLATE SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPRO, INC. ATTN: PATRICK PRINGLE 17 SEVENTEENTH ST. PORT HURON, MI 48060	510(k) NO: K011460 PHONE NO : 810-982-7777	DEVICE: WUJIN #3 TIBIAL BONE PLATE SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPSYBELL S.A.S. ATTN: LUCIO IMPROTA 131 HIGHWOOD DRIVE SOUTH GLASTONBURY, CT 06073	510(k) NO: K010735 PHONE NO : 860-633-8807	DEVICE: SPEEDYBELL SE DECISION MADE: 17-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOPSYBELL S.A.S. ATTN: LUCIO IMPROTA 131 HIGHWOOD DRIVE SOUTH GLASTONBURY, CT 06073	510(k) NO: K011075 PHONE NO : 860-633-8807	DEVICE: EASYBELL SE DECISION MADE: 27-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOPSYBELL S.A.S. ATTN: LUCIO IMPROTA 131 HIGHWOOD DRIVE SOUTH GLASTONBURY, CT 06073	510(k) NO: K011104 PHONE NO : 860-633-8807	DEVICE: OSTEOBELL SE DECISION MADE: 31-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSAFE LABORATORIES, INC. TIMULATING HORMONE (TSH) ATTN: JACK A MAGGIORE 100 FIELD DRIVE SUITE 240 LAKE FOREST, IL 60045	510(k) NO: K003752 PHONE NO : 773-693-0400	DEVICE: BIOSAFE CAPILLARY BLOOD TRANSPORT SYSTEM FOR TESTING THYROID S SE DECISION MADE: 23-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSAFE LABORATORIES, INC. AND TRANSPORT SYSTEM) ATTN: LAURIE A WATERS 100 FIELD DRIVE SUITE 240 LAKE FOREST, IL 60045	510(k) NO: K011525 PHONE NO : 847-234-8111	DEVICE: SAFE AT HOME TSH (THYROID STIMULATING HORMONE BLOOD COLLECTION SE DECISION MADE: 16-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
BIOSENSE WEBSTER, INC. ATTN: AMY WALTERS 3333 DIAMOND CANYON RD. DIAMOND BAR, CA 91765	510(k) NO: K013083 PHONE NO : 909-839-8804	DEVICE: CARTO XP EP NAVIGATION SYSTEM SE DECISION MADE: 21-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSITE DIAGNOSTICS ATTN: JEFFREY R DAHLEN 11030 ROSELLE ST. SAN DIEGO, CA 92121	510(k) NO: K010266 PHONE NO : 858-455-4808	DEVICE: TRIAGE B-TYPE NATRIURETIC PEPTIDE (BNP) TEST, CATALOG #98000 SE DECISION MADE: 16-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSITE DIAGNOSTICS ATTN: JEFFREY R DAHLEN 11030 ROSELLE ST. SAN DIEGO, CA 92121	510(k) NO: K012999 PHONE NO : 858-455-4808	DEVICE: TRIAGE TOX DRUG SCREEN CONTROLS, CATALOG #94001 SE DECISION MADE: 03-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSITE DIAGNOSTICS LOG #94002 ATTN: JEFFREY R DAHLEN 11030 ROSELLE ST. SAN DIEGO, CA 92121	510(k) NO: K013002 PHONE NO : 858-455-4808	DEVICE: TRIAGE TOX DRUG SCREEN CALIBRATION VERIFICATION CONTROLS, CATA SE DECISION MADE: 03-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA

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
BIOSOUND ESAOTE, INC. ATTN: COLLEEN HITTLE 8000 CASTLEWAY DR. INDIANAPOLIS, IN 46250	510(k) NO: K010405 PHONE NO : 317-849-1793	DEVICE: 7230 ULTRASOUND IMAGING SYSTEM WITH TEI SE DECISION MADE: 13-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSOUND ESAOTE, INC. ATTN: COLLEEN HITTLE 8000 CASTLEWAY DR. INDIANAPOLIS, IN 46250	510(k) NO: K012728 PHONE NO : 317-849-1793	DEVICE: E-SCAN MRI SYSTEM SE DECISION MADE: 29-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSPHERE MEDICAL ATTN: JOHN BONASERA 1050 HINGHAM STREET ROCKLAND, MA 02370	510(k) NO: K003105 PHONE NO : 781-681-7900	DEVICE: BIOSPHERE MEDICAL INFUSION CATHETER SE DECISION MADE: 22-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOSPHERE MEDICAL, INC. ATTN: JOHN D BONASERA 1050 HINGHAM STREET ROCKLAND, MA 02370	510(k) NO: K010026 PHONE NO : 781-681-7985	DEVICE: EMBOGOLD MICROSPHERE SE DECISION MADE: 21-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOTECH ATLANTIC, INC. ATTN: FRANCIS LEE BAY F, 6 INDUSTRIAL WAY WEST EATONTOWN, NJ 07724	510(k) NO: K013194 PHONE NO : 732-389-4789	DEVICE: UNIMARK HCG COMBO PREGNANCY TEST SE DECISION MADE: 10-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BIOTEQUE AMERICA, INC. ATTN: DENIS DORSEY 340 EAST MAPLE AVE., #204-C LANGHORNE, PA 19047	510(k) NO: K003380 PHONE NO : 215-750-8071	DEVICE: BIOTEQUE VAGINAL DILATOR SE DECISION MADE: 29-JAN-2001 510(k) STATEMENT
BIOTEQUE AMERICA, INC. ATTN: DENIS DORSEY 340 EAST MAPLE AVE., #204-C LANGHORNE, PA 19047	510(k) NO: K013289 PHONE NO : 215-750-8071	DEVICE: BIOTEQUE VAGINAL PESSARIES SE DECISION MADE: 27-DEC-2001 510(k) STATEMENT
BIOTEQUE CORP. ATTN: ALLEN REICH 900 N. SWITZER CANYON DR. #142 FLAGGSTAFF, 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
BIOTRONIK, INC. ATTN: JON BRUMBAUGH 6024 JEAN RD. LAKE OSWEGO, OR 97035-5369	510(k) NO: K003072 PHONE NO : 888-345-0374	DEVICE: PACING LEADS, GUIDE WIRES, AND VARIOUS ACCESSORIES SE DECISION MADE: 09-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA

BIOTRONIK, INC. ATTN: JON BURMBAUGH 6024 JEAN RD. LAKE OSWEGO, OR 97035-5369	510(k) NO: K003454 PHONE NO : 888-345-0374	DEVICE: A1-CS-SB Y-ADAPTER, MODEL 124 871 SE DECISION MADE: 18-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BISCO, INC. ATTN: CYNDY ORIS 1100 WEST IRVING PARK RD. SCHAUMBURG, IL 60193	510(k) NO: K010196 PHONE NO : 847-534-6000	DEVICE: TOTAL CURE SE DECISION MADE: 05-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BISCO, INC. ATTN: CYNDY ORIS 1100 WEST IRVING PARK RD. SCHAUMBURG, IL 60193	510(k) NO: K011159 PHONE NO : 847-534-6146	DEVICE: ONE-STEP PLUS SE DECISION MADE: 08-JUN-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
BKG OPTHALMICS USA, INC. ATTN: ART WARD 962 ALLEGRO LANE APOLLO BEACH, FL 33572	510(k) NO: K013151 PHONE NO : 813-645-2855	DEVICE: ASMOTOM AUTOMATED TREPHINE SYSTEM SE DECISION MADE: 14-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BLACKSTONE MEDICAL, INC. NECTOR ATTN: ALAN LOMBARDO 90 BROOKSDALE DR. SPRINGFIELD, MA 01104	510(k) NO: K003735 PHONE NO : 973-633-9968	DEVICE: BLACKSTONE SPINAL FIXATION SYSTEM, SECOND-GENERATION CROSS-CON SE DECISION MADE: 08-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BLEASE MEDICAL EQUIPMENT LTD. 60 AND 690 ATTN: ART WARD 962 ALLEGRO LANE APOLLO BEACH, FL 33572	510(k) NO: K003251 PHONE NO : 813-645-2855	DEVICE: BLEASE FRONTLINE PLUS RANGE, ANESTHESIA MACHINES, MODEL 440, 5 SE DECISION MADE: 23-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BODYSTAT LTD. ATTN: I.J. MEEUWSEN PO BOX 50 DOUGLAS ISLE OF MAN BRITISH ISLES,	510(k) NO: K002835 PHONE NO : 446 246 29571	DEVICE: BODYSTAT SE DECISION MADE: 03-JUL-2001 510(k) STATEMENT

BONUTTI RESEARCH, INC. ATTN: PATRICK BALSMANN 2600 SOUTH RANEY P.O. BOX 1367 EFFINGHAM, IL 62401	510(k) NO: K010479 PHONE NO : 217-342-3412	DEVICE: MULTITAK CONICAL TIP BONE SOFT TISSUE SUTURE ANCHOR SE DECISION MADE: 08-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BONUTTI RESEARCH, INC. ATTN: PATRICK BALSMANN P.O. BOX 1367 EFFINGHAM, IL 62401	510(k) NO: K012465 PHONE NO : 217-342-3412	DEVICE: MULTITAK SPLINTER 3.0 MM RESORBABLE ANCHOR SE DECISION MADE: 29-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BONUTTI RESEARCH, INC. ATTN: PATRICK BALSMANN 2600 SOUTH RANEY P.O. BOX 1367 EFFINGHAM, IL 62401	510(k) NO: K013177 PHONE NO : 217-342-3412	DEVICE: MULTITAK SUTURE SNAP SYSTEM SE DECISION MADE: 19-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON MEDICAL TECHNOLOGIES, INC. ATTN: CESIDIO TEMPESTA 591 NORTH AVE., SUITE 5 WAKEFIELD, MA 01880-1641	510(k) NO: K010955 PHONE NO : 781-213-9200	DEVICE: BMT ANSCORE HEALTH MANAGEMENT SYSTEM SE DECISION MADE: 26-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC ATTN: ANDREA L RUTH 2710 ORCHARD PARKWAY SAN JOSE, CA 95134	510(k) NO: K013866 PHONE NO : 408-895-3625	DEVICE: CONVOY ADVANCED DELIVERY SHEATH KIT SE DECISION MADE: 14-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: ANDREA J BOUMIS 2710 ORCHARD PKWY. SAN JOSE, CA 95134	510(k) NO: K003362 PHONE NO : 408-895-3625	DEVICE: ASTRONOMER+WITH SLD SE DECISION MADE: 01-MAR-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
BOSTON SCIENTIFIC CORP. ATTN: THERESA A MCGOVERN ONE BOSTON SCIENTIFIC PL. NATICK, MA 01760-1537	510(k) NO: K003839 PHONE NO : 508-652-5430	DEVICE: CENTRAL VENOUS CATHETER SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: JODI L GREENIZEN ONE BOSTON SCIENTIFIC PL. NATICK, MA 01760-1537	510(k) NO: K003929 PHONE NO : 508-652-5008	DEVICE: NIROYAL BILIARY PREMOUNTED STENT SYSTEM SE DECISION MADE: 22-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP. ATTN: LINDA J VARROSO ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760	510(k) NO: K010002 PHONE NO : 508-652-5192	DEVICE: CONTOUR POLARIS URETERAL STENT SE DECISION MADE: 22-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: LISA M QUAGLIA ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760	510(k) NO: K010610 PHONE NO : 508-650-8267	DEVICE: RAPID EXCHANGE BIOPSY CAP AND LOCKING DEVICE #4526 & 4527 SE DECISION MADE: 27-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: TODD KORNMANN ONE SCIMED PLACE MAPLE GROVE, MN 55311-1566	510(k) NO: K010874 PHONE NO : 763-694-5857	DEVICE: 6F MACH 1, MODEL 34356-XXX SE DECISION MADE: 21-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. L PROBE MODEL 1594X ATTN: ANDREA L RUTH 2710 ORCHARD PARKWAY SAN JOSE, CA 95134	510(k) NO: K010956 PHONE NO : 408-895-3625	DEVICE: COBRA 1/2 FLEX SURGICAL PROBE, MODEL 1593X; COBRA FLEX SURGICA SE DECISION MADE: 13-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: LIAS M QUAGLIA ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760	510(k) NO: K010993 PHONE NO : 508-650-8267	DEVICE: ALIEN RX MICRO CANNULA, MODEL 4530 SE DECISION MADE: 30-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: JENNIFER BOLTON ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760	510(k) NO: K011889 PHONE NO : 508-652-5972	DEVICE: ULTRA -THIN SDS BALLOON DILATATION CATHETER SE DECISION MADE: 21-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: JODI LYNN GREENIZEN ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760	510(k) NO: K011906 PHONE NO : 508-652-5008	DEVICE: BACK-UP MEIER GUIDEWIRE SE DECISION MADE: 13-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: JENNIFER BOLTON ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760	510(k) NO: K011909 PHONE NO : 508-652-5972	DEVICE: ULTRA-THIN SDS BALLOON DILATATION CATHETER SE DECISION MADE: 28-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. 40050X1 ATTN: ROBERT J MICHALIK ONE BOSTON SCIENTIFIC PL. NATICK, MA 01760-1537	510(k) NO: K011965 PHONE NO : 508-650-8000	DEVICE: IMAGER II UROLOGY TORQUE CATHETER, MODEL 40030X1, 40040X1, AND SE DECISION MADE: 13-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA

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

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

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

BOSTON SCIENTIFIC CORP.
E
ATTN: KATHLEEN MORAHAN
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760-1537

510(k) NO: K012752
PHONE NO : 508-652-5942

DEVICE: WALLSTENT RX BILIARY ENDOPROSTHESES, MODELS 6961-6972 INCLUSIV

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

BOSTON SCIENTIFIC CORP.
816, 1820, 1821, 1825, 1826, 1830, 1831, 1835, 1836
ATTN: JAMES D MCMAHON
ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760-1537

510(k) NO: K012864
PHONE NO : 508-652-5566

DEVICE: INTERJECT INJECTION THERAPY NEEDLE, MODELS 1810, 1811, 1815, 1

SE DECISION MADE: 24-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ENT SYSTEM, ULTRAFLEX TRACHEOBRONCHIAL STENT SYSTEM
ATTN: KATHLEEN MORAHAN
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760-1537

510(k) NO: K012883
PHONE NO : 508-650-5942

DEVICE: ULTRAFLEX ESOPHAGEAL STENT SYSTEM, ULTRAFLEX DIAMONDBILIARY ST

SE DECISION MADE: 12-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ATTN: LISA M QUAGLIA
ONE BOSTON SCIENTIFIC PL.
NATICK, MA 01760-1537

510(k) NO: K013153
PHONE NO : 508-650-8267

DEVICE: AUTOTOME RX MODEL # 4515, 4516
SE DECISION MADE: 19-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC SCIMED, INC.
L DELIVERY SYSTEM, MODEL 71-XXX
ATTN: TODD KORNMANN
ONE SCIMED PLACE
MAPLE GROVE, MN 55311

510(k) NO: K012822
PHONE NO : 763-494-2467

DEVICE: MODIFICIATION TO: BILIARY WALLSTENT ENDOPROSTHEIS WITH MONORAI

SE DECISION MADE: 24-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC, TARGET
ATTN: IRENE JAWORSKI
47900 BAYSIDE PARKWAY
FREMONT, CA 94538

510(k) NO: K010707
PHONE NO : 510-440-7700

DEVICE: ATLANTIS SR PLUS CORONARY IMAGING CATHETER, MODEL 35975
SE DECISION MADE: 29-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC, TARGET
ATTN: ROXANE K BAXTER
47900 BAYSIDE PARKWAY
FREMONT, CA 94538

510(k) NO: K010853
PHONE NO : 510-624-2105

DEVICE: GUIDER SOFTIP GUIDING CATHETER XF 5F
SE DECISION MADE: 18-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC, TARGET
168189
ATTN: GEORGE J PRENDERGAST
47900 BAYSIDE PARKWAY
FREMONT, CA 94538

510(k) NO: K013789
PHONE NO : 510-440-7604

DEVICE: EXCELSIOR SL-10 MICROCATHETER, MODELS 168581, 168381, 168181,

SE DECISION MADE: 06-DEC-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
BOSTON SCIENTIFIC/MEDI-TECH ATTN: NICHOLAS CONDAKES ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760-1537	510(k) NO: K012948 PHONE NO : 508-652-5003	DEVICE: MODIFICATION TO VAXCEL DIALYSIS CATHETER SE DECISION MADE: 03-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC/MEDI-TECH AFT ATTN: JENNIFER BOLTON ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760-1537	510(k) NO: K012952 PHONE NO : 508-652-5972	DEVICE: HEMASHIELD GOLD WOVEN DOUBLE VELOUR VASCULAR GRAFT - BRANCH GR SE DECISION MADE: 02-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC/SCIMED ATTN: CANDICE BURNS ONE SCIMED PLACE MAPLE GROVE, MN 55311-1566	510(k) NO: K012216 PHONE NO : 763-494-2845	DEVICE: NIROYAL BILIARY PREMOUNTED STENT SYSTEM SE DECISION MADE: 17-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB AG ATTN: STEFAN VILSMEIER AMMERTHALSTRASSE 8 HEIMSTETTEN,	510(k) NO: K003589 PHONE NO : 498 999 15680	DEVICE: VECTORVISION CRANIAL, VECTORVISION SPINAL, VECTORVISION ENT SE DECISION MADE: 21-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB AG ATTN: STEFAN VILSMEIER AMMERTHALSTRASSE 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: 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
BRAINLAB, AG ATTN: STEFAN VILSMELIER AMMERTHALSTRASSE 8 HEIMSTETTEN,	510(k) NO: K003285 PHONE NO : 498 999 1568-0	DEVICE: EXAC TRAC 2.0 (NOVALIS BODY MODULE) SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB, AG ATTN: RAINER BIRKENBACH AMMERTHALSTRASSE 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
AMMERTHALSTRASSE 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

BRAINLAB, AG
ATTN: RAINER BIRKENBACH
AMMERTHALSTRASSE 8
HEIMSTETTEN,
510(k) NO: K010968
PHONE NO : 498 999 15680
DEVICE: VECTORVISION CT/FLUORO
SE DECISION MADE: 30-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRANAN MEDICAL CORP.
, AND PC12
ATTN: RAPHAEL WONG
10015 MUIRLANDS RD., SUITE E
IRVINE, CA 92618
510(k) NO: K004034
PHONE NO : 949-598-7166
DEVICE: MONITECT MULTIPLE DRUG SCREEN TESTS, MODEL BC12,BC14,TC10,PC11
SE DECISION MADE: 08-MAR-2001
510(k) STATEMENT

BRANAN MEDICAL CORP.
L MC21 AND MD21
ATTN: RAPHAEL WONG
10015 MUIRLANDS RD., SUITE E
IRVINE, CA 92618
510(k) NO: K010734
PHONE NO : 949-598-7166
DEVICE: BRANAN MEDICAL CORPERATION MONITECT TCA DRUG SCREEN TEST, MODE
SE DECISION MADE: 30-JUL-2001
510(k) STATEMENT

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, FASI
SE DECISION MADE: 04-SEP-2001
510(k) STATEMENT

BRANAN MEDICAL CORP.
ATTN: RAPHAEL WONG
10015 MUIRLANDS RD., SUITE E
IRVINE, CA 92618
510(k) NO: K013124
PHONE NO : 949-598-7166
DEVICE: MODIFICATION TO SCOOPER DRUG/ADULTERATION TEST CUP
SE DECISION MADE: 07-NOV-2001
510(k) STATEMENT

BRAUN GMBH
ATTN: FRED SCHLADOR
6183 PASEO DEL MORTE
SUITE 150
CARLSBAD, CA 92009
510(k) NO: K003732
PHONE NO : 760-929-2170
DEVICE: BRAUN PRECISION SENSOR, MODEL BP 2000 SERIES
SE DECISION MADE: 16-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRAUN GMBH
ATTN: FRED SCHLADOR
6183 PASEO DEL MORTE
SUITE 150
CARLSBAD, CA 92009
510(k) NO: K012035
PHONE NO : 760-929-2170
DEVICE: BRAUN PRECISION SENSOR PRO, MODEL BP 2590
SE DECISION MADE: 27-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

BREG, INC.
ATTN: KATHLEEN BARBER
2611 COMMERCE WAY
VISTA, CA 92083
510(k) NO: K013928
PHONE NO : 760-599-3000
DEVICE: PAIN CARE 3200
SE DECISION MADE: 03-DEC-2001
510(k) STATEMENT

BRENTWOOD MEDICAL TECHNOLOGY CORP. 510(k) NO: K010505
ATTN: RUOMEI ZHANG PHONE NO : 310-530-5955
3300 FUJITA STREET
TORRANCE, CA 90505
DEVICE: TELEMED 12 LEAD RESTING ECG ANALYSIS LIBRARY
SE DECISION MADE: 09-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRIDGER BIOMED, INC. 510(k) NO: K003906
ATTN: BRUCE G RUEFER PHONE NO : 406-586-7666
2430 NORTH 7TH AVE., SUITE 4
BOZEMAN, MT 59715
DEVICE: MODIFICATION TO FLUROTEX SURGICAL MESH
SE DECISION MADE: 26-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRIDGER BIOMED, INC. 510(k) NO: K003917
ATTN: BRUCE G RUEFER PHONE NO : 406-586-7666
2430 NORTH 7TH AVE., SUITE 4
BOZEMAN, MT 59715
DEVICE: MODIFICATION TO FLUOROTEX II SURGICAL MESH
SE DECISION MADE: 26-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRIGHTWAY HOLDINGS SDN. BHD. 510(k) NO: K010856
WITH PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS) TESTED
ATTN: G. BASKARAN PHONE NO : 603 334 31007
LOT 1559, JALAN ISTIMEWA
BATU BELAH, KLANG
SELANGOR DARUL EHSAN,
DEVICE: STERILE BRIGHTWAY BRAND POWER-FREE, LATEX EXAMINATION GLOVES,
SE DECISION MADE: 06-JUN-2001
510(k) STATEMENT

BRIGHTWAY HOLDINGS SDN. BHD. 510(k) NO: K011728
-STERILE, PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS) (
ATTN: G. BASKARAN PHONE NO : 603 334 31007
LOT 1559, JALAN ISTIMEWA,
BATU BELAH
KLANG, SELANGOR,
DEVICE: BRIGHTWAY BRAND POWDER FREE LATEX EXAMINATION GLOVES, BLUE NON
SE DECISION MADE: 09-JUL-2001
510(k) STATEMENT

BRITESMILE, INC. 510(k) NO: K010935
ATTN: SHEILA HEMEON-HEYER PHONE NO : 508-643-0434
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760
DEVICE: BRITESMILE BARRIER MATERIAL
SE DECISION MADE: 05-SEP-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRITT CORP., INC. 510(k) NO: K003828
ATTN: J J BRITTON PHONE NO : 732-817-1122
16 CREST DR.
COLTS NECK, NJ 07722
DEVICE: VASO PRESS DVT FOOT GARMENT #VP 520
SE DECISION MADE: 18-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

BROMAC ASSISTIVE TECHNOLOGY 510(k) NO: K012345
ATTN: DAVID K BROWN PHONE NO : 661-264-2525
15845 SWEETAIRE AVE.
LANCASTER, CA 93535
DEVICE: NEW HEIGHTS ELECTRIC ELEVATING MANUAL WHEELCHAIR
SE DECISION MADE: 03-OCT-2001
510(k) STATEMENT

BRONCUS TECHNOLOGIES, INC. 510(k) NO: K010649
ATTN: TIMOTHY R WILLIAMS PHONE NO : 650-428-1600
1400N SHORELINE BLVD.
BLDG. A, SUITE 8
MOUNTAIN VIEW, CA 94043
DEVICE: EXHALE DOPPLER SYSTEM
SE DECISION MADE: 20-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

BRONCUS TECHNOLOGIES, INC. 510(k) NO: K011267
ATTN: TIM R WILLIAMS PHONE NO : 650-428-1600
1400N SHORELINE BLVD.
BLDG. A, SUITE 8
MOUNTAIN VIEW, CA 94043

DEVICE: EXHALE RF PROBE
SE DECISION MADE: 08-MAY-2001

510(k) SUMMARY AVAILABLE FROM FDA

BRONCUS TECHNOLOGIES, INC. 510(k) NO: K013111
ATTN: TIMOTHY R WILLIAMS PHONE NO : 650-428-1600
1400 N SHORELINE BLVD.
BLDG. A, SUITE 8
MOUNTAIN VIEW, CA 94043

DEVICE: EXHALE PROBE
SE DECISION MADE: 01-OCT-2001

510(k) SUMMARY AVAILABLE FROM FDA

BRUNO INDEPENDENT LIVING AIDS, INC510(k) NO: K011227
ATTN: RICHARD A KELLER PHONE NO : 262-953-5336
1780 EXECUTIVE DRIVE
P.O. BOX 84
OCONOMOWOC, WI 53066

DEVICE: REGAL MOTOTRIZED 3 WHEELED VEHICLE
SE DECISION MADE: 11-MAY-2001

510(k) STATEMENT

BUCK MEDICAL RESEARCH 510(k) NO: K010343
D, 3.308, 3.310,3.312, 3.314 3.316
ATTN: REBECCA ELLIS PHONE NO : 214-522-5780
2811 LEMMON AVE., SUITE 201
DALLAS, TX 75204

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

BUSSE HOSPITAL DISPOSABLES, INC. 510(k) NO: K010835
UMBILICAL CORD CLAMP, NON-STERILE, MODEL 385
ATTN: VICKI ATOR PHONE NO : 631-435-4711
75 ARKAY DR.
HAUPPAUGE, NY 11788

DEVICE: POSI-GRIP UMBILICAL CORD CLAMP, STERILE, MODEL 384, POSI-GRIP

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

BYPASS LTD. 510(k) NO: K011589
064, CORLINK AAD (2.0 TO 4.0 MM OUTER DIAMETER VESSELS), M
ATTN: JONATHAN S KAHAN PHONE NO : 202-637-5910
555 THIRTEENTH STREET NW
WASHINGTON, DC 20004-1109

DEVICE: CORLINK AAD (3.5 TO 6.0 M M OUTER DIAMETER VESSELS),MODEL 200-

SE DECISION MADE: 26-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC. 510(k) NO: K003186
ATTN: BETH A ZIS PHONE NO : 978-262-4866
129 CONCORD RD.
BILLERICA, MA 01821

DEVICE: BARD MEMOTHERM ENDOSCOPIC BILIARY STENT
SE DECISION MADE: 09-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC. 510(k) NO: K003289
); BARDEX LUBRI-SIL TEMPERATURE-SENSING FOLEY CATHETER (LU
ATTN: GEORGE C ABERNATHY PHONE NO : 770-784-6454
8195 INDUSTRIAL BLVD.
COVINGTON, GA 30014

DEVICE: BARDEX LATEX-FREE TEMPERATURE-SENSING FOLEY CATHETER (UNCOATED

SE DECISION MADE: 05-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.
ATTN: CAROL VIERLING
13183 HARLAND DRIVE
COVINGTON, GA 30014
510(k) NO: K003793
PHONE NO : 770-385-2347
DEVICE: BARD LUMINEXX BILIARY STENT
SE DECISION MADE: 05-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.
ATTN: BETH A ZIS
129 CONCORD ROAD,
BUILDING 3
BILLERICA, MA 01821
510(k) NO: K003956
PHONE NO : 978-262-4866
DEVICE: BARD ENDOCINCH SUTURING SYSTEM # 000452; 000454; 000595
SE DECISION MADE: 05-JAN-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 UTRAVERSE 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

C.R. BARD, INC.
#5631000 CATHETERLESS TRAY-GENERIC (COMBINED WITH CATHETR
ATTN: PEGGY KEIFFER
5425 WEST AMELIA EARHART DR.
SALT LAKE CITY, UT 84116
510(k) NO: K010567
PHONE NO : 801-595-0700
DEVICE: OPTIFLOW CATHETER #5641190 CATHETER ONLY #5643150 CATHETER KIT
SE DECISION MADE: 28-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.
ATTN: PEGGY KEIFFER
5425 WEST AMELIA EARHART DR.
SALT LAKE CITY, UT 84116
510(k) NO: K010778
PHONE NO : 801-595-0700
DEVICE: NIAGARA SLIM-CATH
SE DECISION MADE: 13-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.
ATTN: PEGGY KEIFFER
5425 WEST AMELIA EARHART DR.
SALT LAKE CITY, UT 84116
510(k) NO: K011015
PHONE NO : 801-595-0700
DEVICE: CATHETER REPAIR KIT WITH REPLACEMENT CONNECTOR, MODEL 5587000
SE DECISION MADE: 22-JUN-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; POL
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

C.R. BARD, INC. 510(k) NO: K013144
UAL PORT WIZARD FEEDING/DECOMPRESSION TUBE, MODEL 00220W
ATTN: MARION GORDON PHONE NO : 978-262-4867
129 CONCORD ROAD
BUILDING 3
BILLERICA, MA 01821

DEVICE: DUAL PORT WIZARD LOW PROFILE REPLACEMENT GASTROSTOMY DEVICE; D
SE DECISION MADE: 19-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

CADUCEUS HEALTH CARE LTD. 510(k) NO: K002514
ATTN: BARRY MARTIN PHONE NO : 902 425 5054
1809 BARRINGTON ST. STE 708
HALIFAX NS,

DEVICE: CADHEALTH SYSTEM, MODEL CHP-001
SE DECISION MADE: 31-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAIRD TECHNOLOGY 510(k) NO: K012686
ATTN: JAMES H BROWN PHONE NO : 803-736-1289
205 CAMDEN CHASE
COLUMBIA, SC 29223

DEVICE: CAIRD TECHNOLOGY HOLTER 2000
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAIRE, INC. 510(k) NO: K013251
ATTN: ROGER BRIESE PHONE NO : 952-882-5071
3505 COUNTY RD. 42 WEST
BURNSVILLE, MN 55306-3803

DEVICE: SPIRIT 300
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CALIFORNIA MEDICAL LABORATORIES, I510(k) NO: K002019
E OR GUIDEWIRE STYLET
ATTN: MEHMET BICAKCI PHONE NO : 949-553-9414
2681 KELVIN AVENUE
IRVINE, CA 92614

DEVICE: RETROGRADE CARDIOPLEGIA CANNULA, SELF-INFLATING, WITH MALLEABL
SE DECISION MADE: 30-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

CALIFORNIA MEDICAL LABORATORIES, I510(k) NO: K010974
BLE OR GUIDWIRE STYLET
ATTN: MEHMET BICAKCI PHONE NO : 714-556-7365
1570 SUNLAND LANE
COSTA MESA, CA 92626

DEVICE: RETROGRADE CARDIOPLEGIA CANNULA, MANUAL-INFLATING, WITH MALLEA
SE DECISION MADE: 18-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAMBRIDGE DIAGNOSTICS IRELAND, LTD510(k) NO: K013907
ATTN: AVRIL MURRAY PHONE NO : 011 353 91757534
MERVUE BUSINESS PARK
GALWAY,

DEVICE: INVERNESS MEDICAL EARLY PREGNANCY TEST
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAMBRIDGE HEART, INC. 510(k) NO: K003492
IAC DIAGNOSTIC SYSTEM; HEARTWAVE ALTERNANS PROCESSING SYS
ATTN: JOHN GREENBAUM PHONE NO : 954-680-2548
20310 SW 48TH ST.
FT. LAUDERDALE, FL 33332

DEVICE: ANALYTIC SPECTRAL METHOD OF ALTERNANS PROCESSING; CH 2000 CARD
SE DECISION MADE: 18-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAMBRIDGE HEART, INC. 510(k) NO: K010756
ATTN: JOHN GREENBAUM PHONE NO : 954-680-2548
20310 SW 48TH ST.
FT. LAUDERDALE, FL 33332

DEVICE: CH 2000 CARDIAC DIAGNOSTIC SYSTEM
SE DECISION MADE: 12-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAMBRIDGE HEART, INC. ATTN: JOHN GREENBAUM 20310 SW 48TH ST. FT. LAUDERDALE, FL 33332	510(k) NO: K010758 PHONE NO : 954-680-2548	DEVICE: HEARTWAVE ALTERNANS PROCESSING SYSTEM, APS SE DECISION MADE: 12-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CAMBRIDGE HEART, INC. ATTN: JOHN GREENBAUM 20310 SW 48TH ST. FT. LAUDERDALE, FL 33332	510(k) NO: K011324 PHONE NO : 954-680-2548	DEVICE: CAMBRIDGE HEART MODEL CH 2000 CARDIAC DIAGNOSTIC SYSTEM SE DECISION MADE: 23-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CAMBRIDGE HEART, INC. M, HEARTWAVE ALTERNANS PROCESSING SYSTEM ATTN: JOHN GREENBAUM 20310 SW 48TH ST. FT. LAUDERDALE, FL 33332	510(k) NO: K012206 PHONE NO : 954-680-2548	DEVICE: ALTERNANAS PROCESSING SYSTEM, CH 2000 CARDIAC DIAGNOSTIC SYSTE SE DECISION MADE: 12-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
CAMBRIDGE HEART, INC. PS ATTN: JOHN GREENBAUM 20310 SW 48TH ST. FT. LAUDERDALE, FL 33332	510(k) NO: K013564 PHONE NO : 954-680-2548	DEVICE: MODIFICATION TO HEARTWAVE ALTERNANS PROCESSING SYSTEM, MODEL A SE DECISION MADE: 21-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CAMBRIDGE HEART, INC. ATTN: JOHN GREENBAUM 20310 SW 48TH ST. FT. LAUDERDALE, FL 33332	510(k) NO: K013565 PHONE NO : 954-680-2548	DEVICE: CARDIAC DIAGNOSTIC SYSTEM, MODEL CH2000 SE DECISION MADE: 21-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CAMBRIDGE MARKETING, INC. FIELD DRAPE ATTN: JOSEPH B DUNN P.O. 306 813 ELA AVENUE WATERFORD, WI 53185	510(k) NO: K010038 PHONE NO : 262-534-2787	DEVICE: NEEDLE BARN STICK STOPPER WITH SAFETY CAP, IN KIT WITH STERILE SE DECISION MADE: 24-JAN-2001 510(k) STATEMENT
CAMSIGHT CO., INC. ATTN: JAY CHOI 1530 BEACH STREET MONTEBELLO, CA 90640	510(k) NO: K010915 PHONE NO : 323-720-3100	DEVICE: CDMX SE DECISION MADE: 21-MAY-2001 510(k) STATEMENT
CANDELA CORP. ATTN: JOAN CLIFFORD 530 BOSTON POST RD. WAYLAND, MA 01778	510(k) NO: K010104 PHONE NO : 508-358-7637	DEVICE: CANDELA LONG PULSE ND:YAG SE DECISION MADE: 11-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CANDELA CORP. ATTN: JOAN CLIFFORD 530 BOSTON POST RD. WAYLAND, MA 01778	510(k) NO: K011092 PHONE NO : 508-358-7637	DEVICE: CANDELA SPTL-1E PULSED DYE LASER SE DECISION MADE: 09-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA

CANDELA CORP.
ATTN: JOAN CLIFFORD
530 BOSTON POST ROAD
WAYLAND, MA 01778

510(k) NO: K013043
PHONE NO : 508-358-7637

DEVICE: CANDELA CLEARBEAM PULSED DYE LASER
SE DECISION MADE: 11-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

CANE SRL
ATTN: DANIEL KAMM
P.O. BOX 7007
DEERFIELD, IL 60015

510(k) NO: K013807
PHONE NO : 847-374-1727

DEVICE: MICROJET QUARK, MODEL U100 OR U40
SE DECISION MADE: 12-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CANICA DESIGN, INC.
ATTN: GEORGETTE ROY
36 MILL STREET
ALMONTE, ONTARIO,

510(k) NO: K010184
PHONE NO : 613 256 0350

DEVICE: CHESS HAND SURGERY SYSTEM
SE DECISION MADE: 22-JUN-2001
510(k) STATEMENT

CANOPUS MEDICAL SUPPLY CO., LTD.
R
ATTN: ELIZABETH DENG
13808 MAGNOLIA AVE.
CHINO, CA 91710

510(k) NO: K013753
PHONE NO : 909-465-9188

DEVICE: DISPOSABLE POWDER FREE VINYL SYNTHETIC EXAM GLOVES, WHITE COLC

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

CANTERBURY HEALTH LABORATORIES
ATTN: MAURICE OWEN
HAGLEY AVENUE
CHRISTCHURCH, CANTERBURY,

510(k) NO: K011389
PHONE NO : 643 364 0546

DEVICE: HEMOGLOBIN F & A2 CONTROL (BETA-THALASSAEMIA CONTROL)
SE DECISION MADE: 21-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAO GROUP, INC.
ATTN: TRACY S BEST
627 WEST SANDY PARKWAY
SANDY, UT 84070

510(k) NO: K003541
PHONE NO : 801-256-9282

DEVICE: DENLASER, MODEL 800
SE DECISION MADE: 25-JAN-2001
510(k) SUMMARY AVAILABLE FROM FDA

CAPSULE TECHNOLOGIE
ATTN: DANIEL KAMM
PO BOX 7007
DEERFIELD, IL 60015

510(k) NO: K013019
PHONE NO : 847-374-1727

DEVICE: "DATACAPTOR"
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K003876
PHONE NO : 972 894 84600

DEVICE: US SENSOR #CG-930P; TOCO SENSOR CG-940P
SE DECISION MADE: 09-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARD GUARD SCIENTIFIC SURVIVAL, LT
ATTN: LEONID TRACHTENBERG
2 PEKERIS STREET
REHOVOT,

510(k) NO: K010552
PHONE NO : 972 894 84600

DEVICE: CG-900P FETAL/MATERNAL MONITOR
SE DECISION MADE: 11-MAY-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARD GUARD SCIENTIFIC SURVIVAL, LT510(k) NO: K012187
ATTN: LEONID TRACHTENBERG PHONE NO : 972 894 84600
2 PERERIS ST., SCIENCE PARK
REHOVOT,

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

CARD GUARD SCIENTIFIC SURVIVAL, LT510(k) NO: K012223
ATTN: LEONID TRACHTENBERG PHONE NO : 972 894 84600
2 PERERIS ST., SCIENCE PARK
REHOVOT,

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

CARD GUARD SCIENTIFIC SURVIVAL, LT510(k) NO: K013175
ATTN: ALEX GONOROVSKY PHONE NO : 972 8 9484600
2 PEKERIS STREET
REHOVOT,

DEVICE: TM2000 EASYTRACE PLUS RECEIVING CENTER
SE DECISION MADE: 30-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARDIAC SCIENCE, INC. 510(k) NO: K012197
ATTN: SEW-WAH TAY PHONE NO : 952-939-2942
5420 FELTL ROAD
MINNEAPOLIS, MN 55343

DEVICE: POWERHEART CARDIAC RHYTHM MODULE
SE DECISION MADE: 16-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARDIODYNAMICS INTERNATIONAL CORP.510(k) NO: K011439
ATTN: BRIAN PARK PHONE NO : 858-535-0202
6175 NANCY RIDGE DR., #300
SAN DIEGO, CA 92121

DEVICE: MODIFICATION TO BIOZ.COM HEMODYNAMIC MONITOR
SE DECISION MADE: 02-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARDIODYNAMICS INTERNATIONAL CORP.510(k) NO: K011797
ATTN: BRAIN PARK PHONE NO : 858-535-0202
6175 NANCY RIDGE DR., #300
SAN DIEGO, CA 92121

DEVICE: BIOZTECT SENSOR AND BIOZTECT CABLE
SE DECISION MADE: 03-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARDIOFOCUS, INC. 510(k) NO: K011988
ATTN: JOSEPH CURTIS PHONE NO : 508-285-1700
10 COMMERCE WAY
NORTON, MA 02766

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

CARDIOFOCUS, INC. 510(k) NO: K013901
ATTN: JOSEPH CURTIS PHONE NO : 508-285-1700
10 COMMERCE WAY
NORTON, MA 02766

DEVICE: MALLEABLE SURGICAL LIGHTSTIC 180, MODEL 180 (1CM-9CM)
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARDIOMEDICS, INC. 510(k) NO: K010261
ATTN: JOHN HUTCHINS PHONE NO : 949-863-2500
18872 BARDEEN AVE.
IRVINE, CA 92612

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

CARDIONET 510(k) NO: K003707
ATTN: DONALD CANAL PHONE NO : 858-550-0961
6199 CORNERSTONE CT.
EAST # 106
SAN DIEGO, CA 92121

DEVICE: CARDIONET AMBULATORY ECG MONITOR, MODEL CN1000A
SE DECISION MADE: 16-MAY-2001

510(k) SUMMARY AVAILABLE FROM FDA

CARDIONETICS, LTD.
ATTN: BARRY SALL
195 WEST STREET
WALTHAM,, MA 02451
510(k) NO: K010396
PHONE NO : 781-434-4742
DEVICE: C. NET 2100
SE DECISION MADE: 04-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARDIOPULMONARY CORP.
ATTN: JOHN LAVIOLA
200 CASCADE BLVD.
MILFORD, CT 06460
510(k) NO: K011861
PHONE NO : 203-877-1999
DEVICE: BERNOULLI VENTILATOR MANAGEMENT SYSTEM
SE DECISION MADE: 06-NOV-2001
510(k) STATEMENT

CARDIOTHORACIC SYSTEMS, INC.
ATTN: ANNE SCHLAGENHAFT
10600 NORTH TANTAU AVE.
CUPERTINO, CA 95014
510(k) NO: K010117
PHONE NO : 408-366-3261
DEVICE: GUIDANT AXIUS CORONARY SHUNT
SE DECISION MADE: 04-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARES BUILT, INC.
ATTN: TIMOTHY D TELYMONDE
75 MANCHESTER AVENUE
KEYPORT, NJ 07735
510(k) NO: K003238
PHONE NO : 800-358-6370
DEVICE: SOLID STATE X-RAY IMAGING DEVICES
SE DECISION MADE: 01-OCT-2001
510(k) SUMMARY AVAILABLE FROM FDA

CARES BUILT, INC.
ATTN: TIMOTHY TELYMONDE
75 MANCHESTER AVE.
KEYPORT, NJ 07735
510(k) NO: K010391
PHONE NO : 732-739-8900
DEVICE: ATLAS MULTI-PURPOSE DSA SYSTEM
SE DECISION MADE: 12-MAR-2001
510(k) STATEMENT

CARES BUILT, INC.
ATTN: TIMOTHY TELYMONDE
75 MANCHESTER AVE.
KEYPORT, NJ 07735
510(k) NO: K010392
PHONE NO : 732-739-8900
DEVICE: ATHENA REMOTE CONTROLLED RF SYSTEM
SE DECISION MADE: 12-MAR-2001
510(k) STATEMENT

CARES BUILT, INC.
ATTN: TIMOTHY TELYMONDE
75 MANCHESTER AVE.
KEYPORT, NJ 07735
510(k) NO: K010393
PHONE NO : 732-739-8900
DEVICE: APOLLO MOBILE "C" ARM SYSTEM
SE DECISION MADE: 12-MAR-2001
510(k) STATEMENT

CARL ZEISS JENA GMBH
510(k) NO: K011877
DEVICE: FF450 PLUS FUNDUS CAMERA AND VISUPAC DIGITAL IMAGE ARCHIVING S
YSTEM, OR FF450 PLUS VISUPAC SYSTEM
ATTN: JOHNATHAN S KAHAN
555 THIRTEENTH STREET, N.W.
WASHINGTONG, DC 20004-1109
PHONE NO : 202-637-5794
SE DECISION MADE: 26-SEP-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

CARL ZEISS, INC. ATTN: KENNETH M NICOLL ONE ZEISS DR. THORNWOOD, NY 10594	510(k) NO: K013402 PHONE NO : 914-747-1800	DEVICE: VISULAS 532S SE DECISION MADE: 14-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CARRINGTON LABORATORIES, INC. ATTN: KENNETH M YATES 2001 WALNUT HILL LN. IRVING, TX 75038	510(k) NO: K012126 PHONE NO : 972-518-1300	DEVICE: THE SALICEPT ORAL PATCH SE DECISION MADE: 03-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
CATCH, INC. ATTN: MARK E LEGAZ PO BOX 2219 LONGVIEW, WA 98632	510(k) NO: K011689 PHONE NO : 360-577-1062	DEVICE: HOMOGENEOUS ENZYMIC HOMOCYSTEINE REAGENT SE DECISION MADE: 25-JUL-2001 510(k) STATEMENT
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
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
CAVEX HOLLAND B.V. ATTN: RICHARD WOORTMAN 2003 RW HAARLEM PO BOX 852 HARMEN,	510(k) NO: K003791 PHONE NO : 31 23 5307763	DEVICE: CAVEX TEMPORARY CEMENT SE DECISION MADE: 23-JAN-2001 510(k) STATEMENT
CAVEX HOLLAND B.V. ATTN: RICHARD WOORTMAN PO BOX 852 RW HAARLEM (HOLLAND),	510(k) NO: K011419 PHONE NO : 011 312 35307763	DEVICE: CAVEX COLORCHANGE SE DECISION MADE: 16-JUL-2001 510(k) STATEMENT
CAVEX HOLLAND B.V. ATTN: RICHARD WOORTMAN PO BOX 852 RW HAARLEM (HOLLAND),	510(k) NO: K011452 PHONE NO : 011 312 35307763	DEVICE: CAVEX STABISIL SE DECISION MADE: 19-JUL-2001 510(k) STATEMENT
CAVEX HOLLAND B.V. ATTN: RICHARD WOORTMAN PO BOX 852 HAARLEM (HOLLAND),	510(k) NO: K013336 PHONE NO : 011 31 235307763	DEVICE: XANTALGIN CRONO SE DECISION MADE: 29-OCT-2001 510(k) STATEMENT

CBYON, INC. ATTN: KRISHNA SUDHAKARAN 2275 E. BAYSHORE RD SUITE 101 PALO ALTO, CA 94303	510(k) NO: K012886 PHONE NO : 650-842-1800	DEVICE: CBYON SYSTEM WITH IMAGE ENHANCED FLUOROSCOPY MODULE SE DECISION MADE: 09-OCT-2001 510(k) STATEMENT
CD LEYCOM BV LUME CATHETER ATTN: TIM LENIHAN ARGONSTRAAT 116 ZOETERMEER,	510(k) NO: K003020 PHONE NO : 31 79 3621602	DEVICE: CARDIAC FUNCTION LABORATORY; PRESSURE INTERFACE; PRESSURE / VC SE DECISION MADE: 11-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CELLAVISION AB ATTN: CONSTANCE G BUNDY 6740 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	510(k) NO: K003301 PHONE NO : 612-574-1976	DEVICE: DIFFMASTER OCTAVIA AUTOMATIC HEMATOLOGY ANALYZER SE DECISION MADE: 15-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CENTRIX, INC. ATTN: JOHN DISCKO 770 RIVER ROAD SHELTON, CT 06484-5458	510(k) NO: K010133 PHONE NO : 203-929-5582	DEVICE: VERSALUX SE DECISION MADE: 05-APR-2001 510(k) STATEMENT
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
CERVILENZ INC ATTN: JUDY F GORDON 2 DELPHINUS IRVINE, CA 92612	510(k) NO: K011840 PHONE NO : 949-854-6314	DEVICE: CERVILENZ UTERINE MEASURING SOUND SE DECISION MADE: 10-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CHAD THERAPEUTICS, INC. ATTN: KEVIN MCCULLOH 21622 PLUMMER ST. CHATSWORTH, CA 91311	510(k) NO: K010389 PHONE NO : 818-882-0883	DEVICE: CHAD THERAPEUTICS OXYMATIC MODEL 401 AND OXYMATIC MODEL 411 SE DECISION MADE: 23-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CHAD THERAPEUTICS, INC. ATTN: KEVIN MCCULLOH 21622 PLUMMER ST. CHATSWORTH, CA 91311	510(k) NO: K013472 PHONE NO : 818-882-0883	DEVICE: TOTAL O2 SE DECISION MADE: 28-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CHARLES A. SMITH ATTN: CHARLES A SMITH 811 STARLITE DR. LOUISVILLE, KY 40207	510(k) NO: K012446 PHONE NO : 502-969-9652	DEVICE: OFFICE BASED ANESTHESIA MACHINE MRI, MODEL OBA-1 MRI SE DECISION MADE: 03-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA

CHASE MEDICAL, INC. ATTN: DAVE HERNON 1876 FIRMAN DR. RICHARDSON, TX 75081	510(k) NO: K003467 PHONE NO : 972-783-0644	DEVICE: CHASE CARDIOVASCULAR PATCH SE DECISION MADE: 29-JAN-2001 510(k) STATEMENT
CHASE MEDICAL, INC. ATTN: DAVE JERNON 1704 ENTERPRISE DR. ATHENS, TX 75751	510(k) NO: K012248 PHONE NO : 972-783-0644	DEVICE: CHASE CARDIOVASCULAR PATCH SE DECISION MADE: 10-AUG-2001 510(k) STATEMENT
CHASON HEALTHCARE, LLC. ATTN: CHARLES F NEILSON 715 BUCKEYE TERRACE ROCK HILL SC, SC 29732	510(k) NO: K011054 PHONE NO : 803-328-0856	DEVICE: RADS SE DECISION MADE: 30-JUL-2001 510(k) STATEMENT
CHATTANOOGA GROUP, INC. ATTN: CHERYL L BAGWELL 4717 ADAMS ROAD CHATTANOOGA, TN 37343-0489	510(k) NO: K011243 PHONE NO : 423-870-2281	DEVICE: CHATTANOOGA DRY HEAT WHIRLPOOL, MODEL 2000 SE DECISION MADE: 06-JUL-2001 510(k) STATEMENT
CHEEN HOUNG ENT. CO. LTD. 2 ATTN: JAY WANG 23 ALLEY 11 LANE 65 SAN DREEN STREET TAIPEI (SHULIN),	510(k) NO: K003927 PHONE NO : 011 886 226892001	DEVICE: Y2000 MANUAL RESUSCITATOR, MODEL RUGU01/RUG02 AND RUGH01/RUGH0 SE DECISION MADE: 26-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CHEEN HOUNG ENT. CO. LTD. ATTN: JAY WANG 23 SAN DREEN ST., ALLEY 11, LANE 65 TAIPEI (SHULIN),	510(k) NO: K010191 PHONE NO : 886 226 892001	DEVICE: Y2000 POCKET RESCUE SE DECISION MADE: 14-MAR-2001 510(k) STATEMENT
CHEMBIO DIAGNOSTIC SYSTEMS, INC. ATTN: FRAN WHITE 163 CABOT STREET BEVERLY,, MA 01915	510(k) NO: K010244 PHONE NO : 978-927-3808	DEVICE: SURE CHECK OVULATION PREDICTOR SE DECISION MADE: 02-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CHEMBIO DIAGNOSTIC SYSTEMS, INC. ATTN: FRAN WHITE 163 CABOT STREET BEVERLY,, MA 01915	510(k) NO: K011550 PHONE NO : 987-927-3808	DEVICE: HCG STAT PAK ULTRA-FAST SE DECISION MADE: 14-AUG-2001 510(k) STATEMENT
CHEMBIO DIAGNOSTIC SYSTEMS, INC. ATTN: FRAN WHITE 163 CABOT STREET BEVERLY,, MA 01915	510(k) NO: K011551 PHONE NO : 978-927-3808	DEVICE: SURE CHECK PREGNANCY TEST SE DECISION MADE: 14-AUG-2001 510(k) STATEMENT

CHILDREN'S HOSPITAL 510(k) NO: K013458 DEVICE: CRANIAL HELMET
ATTN: CONNIE FICKLIN PHONE NO : 952-946-8080 SE DECISION MADE: 29-OCT-2001
5353 WAYZATA BOULEVARD 510(k) SUMMARY AVAILABLE FROM FDA
MINNEAPOLIS, MN 55416-1334

CHILDREN'S HOSPITAL & MEDICAL CENT510(k) NO: K003035 DEVICE: CLARREN HELMET
ATTN: DAVID J BLOCH PHONE NO : 202-414-9209 SE DECISION MADE: 06-JUN-2001
1301 K STREET, N.W.
SUITE 1100 510(k) SUMMARY AVAILABLE FROM FDA
WASHINGTON, DC 20005

CHROMATICS COLOR SCIENCES INTL., I510(k) NO: K001687 DEVICE: COLORMATE TLC BILITEST SYSTEM
ATTN: THOMAS M TSAKERIS PHONE NO : 301-330-2076 SE DECISION MADE: 13-SEP-2001
16809 BRIARDALE ROAD 510(k) SUMMARY AVAILABLE FROM FDA
ROCKVILLE, MD 20855

CHRONIMED, INC. 510(k) NO: K010039 DEVICE: QUICKTEK BLOOD GLUCOSE SYSTEM, QUICKTEK BLOOD GLUCOSE METER, Q
UICKTEK BLOOD GLUCOSE STRIPS, QUICKTEK CONTROL SOLUTION
ATTN: BRUCE A MACFARLANE PHONE NO : 612-974-4088 SE DECISION MADE: 10-AUG-2001
6214 BURY DR. 510(k) SUMMARY AVAILABLE FROM FDA
EDEN PRAIRIE, MN 55346

CHURCHILL MEDICAL SYSTEMS, INC. 510(k) NO: K011336 DEVICE: PRIMARY SOLUTION SET WITH UNIVERSAL SPIKE, INJECTION SITE AND
MALE LUER LOCK
ATTN: KEITH PAULCH PHONE NO : 603-743-5988 SE DECISION MADE: 12-JUN-2001
87 VENTURE DR. 510(k) SUMMARY AVAILABLE FROM FDA
DOVER, NH 03820

CHURCHILL MEDICAL SYSTEMS, INC. 510(k) NO: K011888 DEVICE: PRESSURE ACTIVATED CHECK VALVE
ATTN: KEITH PALUCH PHONE NO : 603-743-5988 SE DECISION MADE: 10-SEP-2001
87 VENTURE DR. 510(k) SUMMARY AVAILABLE FROM FDA
DOVER, NH 03820

CHURCHILL MEDICAL SYSTEMS, INC. 510(k) NO: K012157 DEVICE: CHURCHILL MEDICAL SYSTEMS STOPCOCK
ATTN: KEITH PALUCH PHONE NO : 603-743-5988 SE DECISION MADE: 11-SEP-2001
87 VENTURE DR. 510(k) SUMMARY AVAILABLE FROM FDA
DOVER, NH 03820

CIBA VISION CORP. 510(k) NO: K003345 DEVICE: AOSEPT PLUS CLEANING AND DISINFECTING SOLUTION
ATTN: STEVEN DOWDLEY PHONE NO : 678-415-4214 SE DECISION MADE: 26-MAR-2001
11460 JOHNS CREEK PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
DULUTH, GA 30097

CIBA VISION CORP. 510(k) NO: K003826 DEVICE: FOCUS DAILIES PROGRESSIVES
ATTN: ALICIA M PLESNARSKI PHONE NO : 678-415-3924 SE DECISION MADE: 08-MAR-2001
11460 JOHNS CREEK PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
DULUTH, GA 30097

CIBA VISION CORP. 510(k) NO: K010636 DEVICE: FOCUS DAILIES (NELFILCON A) ONE-DAY SOFT CONTACT LENSES, FOCUS
DAILIES PROGRESSIVES (NELFILCON A) ONE-DAY SOFT CONTACT
ATTN: ALICIA M PLESNARSKI PHONE NO : 678-415-3924 SE DECISION MADE: 23-MAR-2001
11460 JOHNS CREEK PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
DULUTH, GA 30097

CIBA VISION CORP. 510(k) NO: K012731 DEVICE: SOLO-CARE PLUS MULTIPURPOSE SOLUTION
ATTN: STEVEN DOWDLEY PHONE NO : 687-415-3897 SE DECISION MADE: 26-DEC-2001
11460 JOHNS CREEK PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
DULUTH, GA 30097

CIBA VISION CORP. 510(k) NO: K013512 DEVICE: AOSEPT CLEAR CARE CLEANING AND DISINFECTING SOLUTION
ATTN: STEVEN DOWDLEY PHONE NO : 687-415-3897 SE DECISION MADE: 20-DEC-2001
11460 JOHNS CREEK PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
DULUTH, GA 30097

CIBA-GEIGY CORP. 510(k) NO: K003586 DEVICE: FOCUS DAILIES (NELFILCON A) ONE-DAY CONTACT LENSES
ATTN: STEVEN DOWDLEY PHONE NO : 678-415-3897 SE DECISION MADE: 08-FEB-2001
11460 JOHNS CREEK PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
DULUTH, GA 30136-1518

CIRCON VIDEO 510(k) NO: K011848 DEVICE: CIRCON AEH-4 ELECTROHYDRAULIC LITHOTRIPSY PROBE
ATTN: JERRY CROUTHERS PHONE NO : 805-685-5100 SE DECISION MADE: 11-SEP-2001
6500 HOLLISTER AVE. 510(k) STATEMENT
SANTA BARBARA, CA 93117

CIRCON VIDEO 510(k) NO: K011849 DEVICE: MICRO-6-SERIES (MR-6, MR-6L) URETEROSCOPES, MRO-6 SERIES (MR-6
33, MR-642) URETEROSCOPES, MRO-7 SERIES (MRO-733) URETEROS
ATTN: WAYNE B STERNER PHONE NO : 805-685-5100 SE DECISION MADE: 10-DEC-2001
6500 HOLLISTER AVE. 510(k) SUMMARY AVAILABLE FROM FDA
SANTA BARBARA, CA 93117

CIRCON VIDEO 510(k) NO: K012153 DEVICE: LOWSLEY SUPRAPUBIC TRACTOR
ATTN: WAYNE B STGRNER PHONE NO : 805-685-5100 SE DECISION MADE: 19-SEP-2001
6500 HOLLISTER AVE. 510(k) STATEMENT
SANTA BARBARA, CA 93117

CIRCON VIDEO 510(k) NO: K012265 DEVICE: METAL HALIDE LIGHT SOURCE, MODELS MV-9088-T, MV-9088
ATTN: WAYNE B STERNER PHONE NO : 805-685-5100 SE DECISION MADE: 17-OCT-2001
6500 HOLLISTER AVE. 510(k) STATEMENT
SANTA BARBARA, CA 93117

CIRCON VIDEO 510(k) NO: K012925 DEVICE: DUR-8, MODELS DUR-8
ATTN: WAYNE STERNER PHONE NO : 805-685-5100 SE DECISION MADE: 07-NOV-2001
6500 HOLLISTER AVE. 510(k) STATEMENT
SANTA BARBARA, CA 93117

CIRCON VIDEO
ATTN: WAYNE STERNER
6500 HOLLISTER AVE.
SANTA BARBARA, CA 93117

510(k) NO: K012929
PHONE NO : 805-685-5100

DEVICE: FLEXIBLE PEDIATRIC CYSTOURETEROSCOPE, MODEL AUR- 735
SE DECISION MADE: 19-NOV-2001
510(k) STATEMENT

CIRCON VIDEO
ATTN: WAYNE B STERNER
6500 HOLLISTER AVE.
SANTA BARBARA, CA 93117

510(k) NO: K012951
PHONE NO : 805-685-5100

DEVICE: APN-2 USA SERIES FLEXIBLE CHOLEDOCHOSCOPE
SE DECISION MADE: 09-NOV-2001
510(k) STATEMENT

CIRCULATORY TECHNOLOGY, INC.
VENOUS DRAINAGE, CATALOG NUMBER VACBOX1500
ATTN: YEHUDA TAMARI
21 SINGWORTH ST.
OYSTER BAY, NY 11771

510(k) NO: K012942
PHONE NO : 516-624-2424

DEVICE: THE V BAG, CATALOG NUMBER VB1800; VAC-BOX FOR VACUUM ASSISTED

SE DECISION MADE: 05-NOV-2001
510(k) STATEMENT

CIVCO MEDICAL INSTRUMENTS CO., INC
ATTN: THERESA LEINEN
102 FIRST ST. SOUTH
KALONA, IA 52247

510(k) NO: K013721
PHONE NO : 319-656-4447

DEVICE: SYNTHETIC POLYSIOPRENE ULTRASOUND TRANSDUCER COVER
SE DECISION MADE: 28-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CL-TINTERS
S FOR DAILY WEAR (CLEAR AND TINTED)
ATTN: MARTIN S KNOPF
10 WARRENTON LANE
COLTS NECK, NJ 07722

510(k) NO: K010126
PHONE NO : 732-817-1425

DEVICE: PROSTHETIC, GELFLEX ALPHA, (POLYMACON) HYDROPHILIC CONTACT LEN

SE DECISION MADE: 12-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

CLARUS MEDICAL, LLC.
ATTN: TOM BARTHEL
1000 BOONE AVE. NORTH
MINNEAPOLIS, MN 55427

510(k) NO: K011454
PHONE NO : 763-525-8401

DEVICE: SPINE SCOPE, MODEL 2180
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CLAY-PARK LABS, INC.
ATTN: GARY L YINGLING
1800 MASSACHUSETTS AVE., N.W.
WASHINGTON, DC 20036

510(k) NO: K012203
PHONE NO : 202-778-9124

DEVICE: CLAY-PARK LABS, INC. - LUBRICATING JELLY
SE DECISION MADE: 27-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

CLINICAL CONTROLS DIVISION
ATTN: JAMES F GODFREY
12038 CENTRALIA AVE.
UNIT C
HAWAIIAN GARDENS, CA 90716

510(k) NO: K012855
PHONE NO : 562-809-3389

DEVICE: LIQUISPX LIQUID LIPID CONTROL
SE DECISION MADE: 30-AUG-2001

510(k) STATEMENT

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

CLINICAL INNOVATIONS, INC. ATTN: DEAN WALLACE 6477 SOUTH COTTONWOOD STREET MURRAY, UT 84107	510(k) NO: K003458 PHONE NO : 801-268-8200	DEVICE: SOFT BEAT FETAL HEART RATE ELECTRODE MODEL SBT-7000 SE DECISION MADE: 03-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CLINICAL TECHNOLOGIES, INC. ATTN: BOB JOHNSON 705 E. VIRGINIA WAY SUITE 1 BARSTOW, CA 92311	510(k) NO: K010680 PHONE NO : 760-256-2569	DEVICE: CT SPACER SE DECISION MADE: 23-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CLINIQA CORPORATION COULTER IMMAGE ATTN: CAROL RUGGIERO 1432-B SOUTH MISSION ROAD FALLBROOK, CA 92028	510(k) NO: K013332 PHONE NO : 760-744-1900	DEVICE: LINICAL PROTEIN I CALIBRATION VERIFIERS LEVELS A=E FOR BECKMAN SE DECISION MADE: 20-NOV-2001 510(k) STATEMENT
CLOSURE MEDICAL CORP. ATTN: W. THOMAS STEPHENS 5250 GREENS DAIRY RD. RALEIGH, NC 27616	510(k) NO: K002338 PHONE NO : 919-876-7800	DEVICE: LIQUIDERM LIQUID ADHESIVE BANDAGE SE DECISION MADE: 29-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CMT MEDICAL TECHNOLOGIES, LTD. ATTN: YESHAYAHU RAZ MATAM HIGH TECHNOLOGY CENTER HAIFA,	510(k) NO: K003438 PHONE NO : 972 485 66233	DEVICE: SMART RAD SE DECISION MADE: 03-JUL-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
COALESCENT SURGICAL ATTN: MICHAEL A DANIEL 559 EAST WEDDELL DR. SUNNYVALE, CA 94089	510(k) NO: K012317 PHONE NO : 415-407-0223	DEVICE: COALESCENT SURGICAL U-CLIP SE DECISION MADE: 31-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
COBE CARDIOVASCULAR, INC. ATTN: LYNNE LEONARD 14401 WEST 65TH WAY ARVADA, CO 80004	510(k) NO: K001509 PHONE NO : 303-467-6586	DEVICE: STOCKERT V172 SERIES VENOUS FEMORAL CANNULAE SE DECISION MADE: 26-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
COBE CARDIOVASCULAR, INC. VVR 4000 FILTERED HARDSHELL VENOUS RESERVOIR ATTN: LYNNE LEONARD 14401 WEST 65TH WAY ARVADA, CO 80004	510(k) NO: K004046 PHONE NO : 303-467-6586	DEVICE: COBE VVR 4000 FILTERED HARDSHELL VENOUS RESERVOIR, COBE SMARXI SE DECISION MADE: 26-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA

COBE CARDIOVASCULAR, INC. IOPLEGIA SYSTEM ATTN: LYNNE LEONARD 14401 WEST 65TH WAY ARVADA, CO 80004	510(k) NO: K012763 PHONE NO : 303-467-6586	DEVICE: SORIN BIOMEDICA SMART BCD VANGUARD,SURFACE MODIFIED BLOOD CARD SE DECISION MADE: 15-NOV-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
COBE CARDIOVASCULAR, INC. GENATOR ATTN: SHAWN RIEDEL 14401 WEST 65TH WAY ARVADA, CO 80004	510(k) NO: K013480 PHONE NO : 303-467-6521	DEVICE: COBE SMARXT OPTIMIN SURFACE MODIFIED HOLLOW FIBER MEMBRANE OXY SE DECISION MADE: 16-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CODMAN & SHURTLEFF, INC. ATTN: JAMES M FLAHERTY 325 PARAMOUNT DR. RAYNHAM, MA 02767-0350	510(k) NO: K003322 PHONE NO : 508-880-8404	DEVICE: CODMAN BACTISEAL CATHETERS SE DECISION MADE: 01-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
CODMAN & SHURTLEFF, 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
CODMAN & SHURTLEFF, INC. ATTN: KATHRYN WUNDER 325 PARAMOUNT DR. RAYNHAM, MA 02767-0350	510(k) NO: K013877 PHONE NO : 508-880-8351	DEVICE: CODMAN SLIM-LOC SYSTEM SE DECISION MADE: 19-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
CODONICS, INC. ATTN: GARY J ALLSEBROOK 16303 PANORAMIC WAY SAN LEANDRO, CA 94578-1116	510(k) NO: K003481 PHONE NO : 510-276-2648	DEVICE: CODONICS NP-1660 SERIES MEDICAL PRINTERS, MODEL 1660 SE DECISION MADE: 19-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
COHERENT STAR ATTN: ILIRIJA ENCINAS 1249 QUARRY LANE SUITE 100 PLEASANTON, CA 94566	510(k) NO: K003614 PHONE NO : 925-249-8031	DEVICE: LIGHTSHEER PULSED DIODE ARRAY LASER SYSTEM SE DECISION MADE: 13-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
COLLAGEN MATRIX, INC. ATTN: SHU-TUNG LI 509 COMMERCE STREET FRANKLIN LAKES,, NJ 07417	510(k) NO: K003339 PHONE NO : 201-405-1477	DEVICE: COLLAGEN PERIODONTAL MEMBRANE SE DECISION MADE: 08-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA

COLLAGEN MATRIX, INC. ATTN: SHU-TUNG LI 509 COMMERCE STREET FRANKLIN LAKES,, NJ 07417	510(k) NO: K011695 PHONE NO : 201-405-1477	DEVICE: COLLAGEN DENTAL MEMBRANE SE DECISION MADE: 07-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
COLOURS 'N MOTION ATTN: VICTOR R BOX 1591 SOUTH SINCLAIR ST. ANAHEIM, CA 92806	510(k) NO: K010823 PHONE NO : 714-978-1440	DEVICE: SPAZZ SE DECISION MADE: 27-APR-2001 510(k) STATEMENT
COLTENE/WHALEDENT, INC. ATTN: H.J. VOGELSTEIN 750 CORPORATE DR. MAHWAH, NJ 07430-2009	510(k) NO: K013400 PHONE NO : 201-512-8000	DEVICE: SYNERGY FLOW SE DECISION MADE: 10-DEC-2001 510(k) STATEMENT
COLUMBIA SCIENTIFIC, INC. ATTN: CHARLES D STOCKHAM 8940 OLD ANNAPOLIS RD. COLUMBIA, MD 21045	510(k) NO: K011180 PHONE NO : 410-964-3110	DEVICE: CT/MASTER, VERSION 1.0 SE DECISION MADE: 27-JUN-2001 510(k) STATEMENT
COMPUTER MOTION, INC. ATTN: DAVID THOMAS 130-B CREMONA DR. GOLETA, CA 93117	510(k) NO: K003431 PHONE NO : 805-968-9600	DEVICE: ZEUS ROBOTIC SURGICAL SYSTEM SE DECISION MADE: 05-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
COMPUTER MOTION, INC. ATTN: DAVID THOMAS 130 CREMONA DRIVE, SUITE B GOLETA, CA 93117	510(k) NO: K003661 PHONE NO : 805-968-9600	DEVICE: SOCRATES ROBOTIC TELEMONITORING SYSTEM SE DECISION MADE: 05-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
COMPUTER MOTION, INC. ATTN: DAVID U THOMAS 130 CREMONA DRIVE, SUITE B GOLETA, CA 93117	510(k) NO: K013804 PHONE NO : 805-968-9600	DEVICE: SOCRATES ROBOTIC TELEMONITORING SYSTEM SE DECISION MADE: 10-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
COMPUTERIZED MEDICAL SYSTEMS, INC. ATTN: MICHAEL A PARSONS 1145 CORPORATE LAKE DR. ST. LOUIS, MO 63132-1716	510(k) NO: K013112 PHONE NO : 314-993-0003	DEVICE: FOCAL SIM SE DECISION MADE: 05-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONCENTRIC MEDICAL, INC. ATTN: LINDA BRADLEY 2585 LEGHORN STREET MOUTIAN VIEW, CA 94043	510(k) NO: K003084 PHONE NO : 650-938-2100	DEVICE: CONCENTRIC HYDROPHILIC GUIDEWIRE, MODELS 90011, 90012 SE DECISION MADE: 16-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA

CONCENTRIC MEDICAL, INC. ATTN: LINDA BRADLEY 2585 LEGHORN STREET MOUTIAN VIEW, CA 94043	510(k) NO: K003085 PHONE NO : 650-938-2100	DEVICE: CONCENTRIC GUIDE CATHETER, MODELS 90018, 90020 SE DECISION MADE: 07-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONCENTRIC MEDICAL, INC. ATTN: LINDA BRADLY 2585 LEGHORN STREET MOUTIAN VIEW, CA 94043	510(k) NO: K003086 PHONE NO : 650-938-2100	DEVICE: CONCENTRIC MICRO CATHETER, MODELS 90001 TO 90008 SE DECISION MADE: 16-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONCENTRIC MEDICAL, INC. ATTN: SAM LAZZARA 2585 LEGHORN STREET MOUTIAN VIEW, CA 94043	510(k) NO: K003410 PHONE NO : 650-938-2100	DEVICE: CONCENTRIC RETRIEVER, MODEL 90030 SE DECISION MADE: 22-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONCENTRIC MEDICAL, INC. 0021 (6F), 90022 (7F), 90023 (8F), 90024 (9F) ATTN: SAM LAZZARA 2585 LEGHORN STREET MOUTIAN VIEW, CA 94043	510(k) NO: K003880 PHONE NO : 650-938-2100	DEVICE: CONCENTROC HD GUIDE CATHETER, MODELS 90017 (4F), 90019 (5F), 9 SE DECISION MADE: 16-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONCENTRIC MEDICAL, INC. ATTN: KEVIN MACDONALD 2585 LEGHORN ST. MOUTIAN VIEW, CA 94043	510(k) NO: K010954 PHONE NO : 650-938-2100	DEVICE: CONCENTRIC BALLOON GUIDE CATHETER, MODEL 90031 SE DECISION MADE: 09-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONCEPTION TECHNOLOGIES ATTN: GRACE HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K011462 PHONE NO : 949-262-0411	DEVICE: OIL FOR TISSUE CULTURE SE DECISION MADE: 13-JUN-2001 510(k) STATEMENT
CONCEPTION TECHNOLOGIES ATTN: GRACE HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K011481 PHONE NO : 949-262-0411	DEVICE: 10% PVP; 10% PVP IN EBSS SOLUTION SE DECISION MADE: 02-JUL-2001 510(k) STATEMENT
CONCEPTION TECHNOLOGIES ATTN: GRACE HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K011573 PHONE NO : 949-262-0411	DEVICE: HYALURONIDASE IN HTF MEDIUM; HYALURONIDASE IN EBSS MEDIUM SE DECISION MADE: 02-JUL-2001 510(k) STATEMENT
CONTACT COLOR SRL ATTN: MARIA E DONAWA VIA FONTE DI FAUNO, 22 ROME,	510(k) NO: K011893 PHONE NO : 390 657 82665	DEVICE: COSMETICA (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES SE DECISION MADE: 06-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA

CONTINUUM ELECTRO-OPTICS, INC. WITCHED ND:YAG LASER ATTN: RONALD KOHLHARDT 3150 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051	510(k) NO: K011677 PHONE NO : 408-727-3240	DEVICE: MEDLITE Q-SWITCHED ND:YAG LASER REPLACED BY THE MEDLITE C3 Q-S SE DECISION MADE: 22-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CONTRACT LATEX DIPPERS SDN BHD ATTN: VINAYAGAN RAMALINGAM LOT 5B, 7A & 8A KAWASAN MIEL BATANG KALI, SELANGOR,	510(k) NO: K011012 PHONE NO : 603 807 2714	DEVICE: POWDER FREE NITRILE EXAMINATION GLOVE SE DECISION MADE: 01-MAY-2001 510(k) STATEMENT
COOK UROLOGICAL, INC. ATTN: BRENDA DAVIS 1100 WEST MORGAN ST. P.O. BOX 227 SPENCER, IN 47460	510(k) NO: K011157 PHONE NO : 812-829-6500	DEVICE: COOK IVF CRYOPRESERVATION KIT AND THE COOK IVF THAW KIT SE DECISION MADE: 03-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK VASCULAR, INC. ATTN: THOMAS J KARDOS RT. 66, RIVER RD. P.O. BOX 529 LEECHBURG, PA 15656-0529	510(k) NO: K002958 PHONE NO : 724-845-8621	DEVICE: SHAPEABLE DOPPLER FLOW PROBE SE DECISION MADE: 18-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK VASCULAR, INC. ATTN: THEODORE HEISE RT. 66, RIVER RD. P.O. BOX 529 LEECHBURG, PA 15656	510(k) NO: K010055 PHONE NO : 765-463-7537	DEVICE: COOK VASCULAR ELECTROSURGICAL DISSECTION SHEATH SE DECISION MADE: 14-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: APRIL LAVENDER 925 S. CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K001985 PHONE NO : 812-339-2235	DEVICE: INTRODEUCE DOUBLE LUMEN INTRODUCER SE DECISION MADE: 25-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: APRIL LAVENDER 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K002254 PHONE NO : 812-339-2235	DEVICE: COOK PRESSURE MONITORING CATHETER SE DECISION MADE: 16-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: MARY A GOSSARD 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K002286 PHONE NO : 812-339-2235	DEVICE: LDOB OCCLUSION BALLOON CATHETER SE DECISION MADE: 22-MAR-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: K010016 PHONE NO : 812-339-2235	DEVICE: MELKER CUFFED EMERGENCY CRICOTHYROTOMY CATHETER SE DECISION MADE: 09-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: LISA WEBB 925 S. CURRY PIKE BLOOMINGTON, IN 47401	510(k) NO: K010034 PHONE NO : 812-339-2235	DEVICE: DOUBLE LUMEN URETHANE PICC LINE, MODEL UPICDS- SE DECISION MADE: 24-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: LISA HOPKINS 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K010242 PHONE NO : 812-339-0489	DEVICE: COOK ZILVER BILIARY STENT SE DECISION MADE: 13-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
COOK, INC. ATTN: LISA HOPKINS 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K010601 PHONE NO : 812-339-2235	DEVICE: FANELLI BILIARY STENT SE DECISION MADE: 16-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: APRIL LAVENDER 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K011812 PHONE NO : 812-339-2235	DEVICE: SPECTRUM VENTRICULAR CATHETER SE DECISION MADE: 08-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: HEIDI MASTEN 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K013916 PHONE NO : 812-339-2235	DEVICE: MELKER EMERGENCY CRICOTHYROTOMY CATHETER SET SE DECISION MADE: 20-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
COOLTOUCH CORP. M, MODEL COOLTOUCH, COOLTOUCH II ATTN: DONALD V JOHNSON 9085 FOOTHILLS BOULEVARD ROSEVILLE, CA 95747	510(k) NO: K003715 PHONE NO : 916-677-1912	DEVICE: COOLTOUCH ND:YAG LASER SYSTEM, COOLTOUCH-II ND:YAG LASER SYSTE SE DECISION MADE: 01-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA

COOLTOUCH CORP. :YAG LASER SYSTEM ATTN: DONALD V JOHNSON 9085 FOOTHILLS BOULEVARD ROSEVILLE, CA 95747	510(k) NO: K010316 PHONE NO : 916-677-1900	DEVICE: COOLTOUCH "VARIA" ND:YAG LASER SYSTEM; COOLTOUCH "VARIA-II" ND SE DECISION MADE: 01-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
COPAN DIAGNOSTICS, INC. ATTN: MARY MCNAMARA-CULLINANE 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K001780 PHONE NO : 508-643-0434	DEVICE: COPAN VIRAL TRANSYSTEM SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: CHARLES (CHUCK) J RYAN 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K003920 PHONE NO : 908-412-7446	DEVICE: CORDIS M3 PTA DILATATION CATHETER SE DECISION MADE: 15-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. 6-P306A AND 466-P306B ATTN: KAREN WILK 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K003964 PHONE NO : 908-412-7257	DEVICE: TRAPEASE PERMANENT VENA FILTER AND INTRODUCTION KIT, MODELS 46 SE DECISION MADE: 19-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. L 466-P306A ATTN: KAREN WILK 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K010083 PHONE NO : 908-412-7257	DEVICE: TRAPEASE PERMANENT VENA CAVA FILTER AND INTRODUCTION KIT, MODE SE DECISION MADE: 06-JUN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: CHARLES J RYAN 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K010411 PHONE NO : 908-412-7446	DEVICE: PALMAZ GENESIS TRANSHEPATIC BILLARY STENT AND DELIVERY SYSTEM SE DECISION MADE: 27-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: SAM MIRZA 14201 N.W. 60TH AVE. MIAMI LAKES, FL 33014	510(k) NO: K010445 PHONE NO : 305-824-2007	DEVICE: PRECISE NITINOL STENT TRANSHEPATIC BILLARY SYSTEM SE DECISION MADE: 16-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: CHUCK RYAN 14201 N.W. 60TH AVE. MIAMI LAKES, FL 33014	510(k) NO: K012087 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS 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

CORDIS CORP. TEM ATTN: SAM MIRZA 14201 N.W. 60TH AVE. MIAMI LAKES, FL 33014	510(k) NO: K012993 PHONE NO : 305-824-2007	DEVICE: MODIFICATION TO PRECISE NITINOL STENT TRANSHEPATIC BILIARY SYS SE DECISION MADE: 05-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS EUROPA N.V. 8 DELIVERY SYSTEM ATTN: CHUCK RYAN 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K012056 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT ON SLALOM .01 SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS NEUROVASCULAR, INC. ATTN: AMARILYS MACHADO 14000 N.W. 57TH CT. MIAMI LAKES, FL 33014	510(k) NO: K003925 PHONE NO : 305-512-6493	DEVICE: PROWLER INFUSION CATHETERS WITH PRE-SHAPED TIPS SE DECISION MADE: 08-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS NEUROVASCULAR, INC. ATTN: AMARILYS MACHADO 14000 N.W. 57TH CT. MIAMI LAKES, FL 33014	510(k) NO: K010511 PHONE NO : 305-512-6493	DEVICE: MODIFICATION TO: AGILITY STEERABLE GUIDEWIRES SE DECISION MADE: 01-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS, A JOHNSON & JOHNSON CO. ATTN: CHARLES J RYAN 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K012090 PHONE NO : 908-412-7446	DEVICE: CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STENT SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS, A JOHNSON & JOHNSON CO. ATTN: CHUCK RYAN 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K013581 PHONE NO : 908-412-7446	DEVICE: CORDIS AVIATOR PERIPHERAL DILATATION CATHETER SE DECISION MADE: 28-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORGENIX, INC. ATTN: NANCI DEXTER 12061 TEJON ST. WESTMINISTER, CO 80234	510(k) NO: K001352 PHONE NO : 303-457-4345	DEVICE: REAADS IGG ANTI-PROTHROMBIN SEMI-QUANTITATIVE TEST KIT SE DECISION MADE: 09-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORGENIX, INC. ATTN: NANCI DEXTER 12061 TEJON ST. WESTMINISTER, CO 80234	510(k) NO: K001398 PHONE NO : 303-457-4345	DEVICE: REAADS IGM ANTI-PROTHROMBIN SEMI-QUANTITATIVE TEST KIT SE DECISION MADE: 30-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORGENIX, INC. UANTITATIVE TEST KIT ATTN: NANCI DEXTER 12061 TEJON ST. WESTMINSTER, CO 80234	510(k) NO: K012567 PHONE NO : 303-457-4345	DEVICE: MODIFICATION TO: REAADS ANTI-PHOSPHATIDYLSERINE IGG/IGM SEMI-Q SE DECISION MADE: 23-AUG-2001 510(k) STATEMENT

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-QUANTITIVE 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
CORIN U.S.A. ATTN: JOEL K BATTS 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 BATTS 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
CORIN U.S.A. XX SERIES CATALOGUE NUMBERS ATTN: JOEL BATTS 10500 UNIVERSITY CENTER DR., SUITE 190 TAMPA, FL 33612	510(k) NO: K010776 PHONE NO : 813-977-4469	DEVICE: TRINITY POLYAXIAL SCREW, MEHDIAN SPINAL ROD (6MM), MODEL 159.X SE DECISION MADE: 06-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CORINTHIAN MEDICAL LTD. ATTN: DAGMAR MASER AMSTEL 320-1 AMERSTDAM,	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
CORTECHS LLC ATTN: JEFFREY M ANDERS 6 13TH ST. CHARLESTOWN, MA 02129-2027	510(k) NO: K012563 PHONE NO : 617-241-9588	DEVICE: DEEP GRAY SE DECISION MADE: 02-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA

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
COSMED S.R.L. ATTN: ROBERT SCHIFF 1129 BLOOMFIELD AVENUE WEST CALDWELL, NJ 07006	510(k) NO: K001174 PHONE NO : 973-227-1830	DEVICE: COSMED QUARK SE DECISION MADE: 11-JAN-2001 510(k) STATEMENT
COZART BIOSCIENCE LTD. ATTN: LESLY MOORE 45 MILTON PARK ABINGDON OXFORDSHIRE OX14 4RU,	510(k) NO: K011131 PHONE NO : 012 358 61483	DEVICE: METHADONE MICROPLATE EIA URINE APPLICATION SE DECISION MADE: 31-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
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
CP MEDICAL TERILE ATTN: MARY ANN GREENAWALT 836 N.E. 24TH AVE. PORTLAND, OR 97232	510(k) NO: K013274 PHONE NO : 503-232-1555	DEVICE: MONO-DOX, SYNTHETIC ABSORBABLE POLYDIOXANONE SURGICAL SUTURE,S SE DECISION MADE: 16-NOV-2001 510(k) SUMMARY AVAILABLE FROM FDA
CRESCO TI SYSTEMS AB ATTN: PER E NILSSON 350 GLEN COVE AVENUE GLEN HEAD, NY 11545	510(k) NO: K981052 PHONE NO : 516-759-6390	DEVICE: CRESCO TI IMPLANT CONCEPT SE DECISION MADE: 18-DEC-2001 510(k) STATEMENT
CRITICARE SYSTEMS, INC. ATTN: ALEX KAPLAN 20925 CROSSROADS CIRCLE WAUKESHA, WI 53186	510(k) NO: K012059 PHONE NO : 262-798-8282	DEVICE: 8100/8500 VITAL SIGNS MONITOR SE DECISION MADE: 01-AUG-2001 510(k) SUMMARY AVAILABLE FROM FDA
CRYOMEDICAL SCIENCES, INC. ATTN: E.J. SMITH PO BOX 4341 CROFTON, MD 21114	510(k) NO: K011073 PHONE NO : 410-451-0639	DEVICE: CRYOPLAN SYSTEM SE DECISION MADE: 22-AUG-2001 510(k) STATEMENT
CRYSTAL-SEAL DENTAL IMPLANTS ATTN: CLINT FOLSOM 181 VALLEY PARKWAY PELHAM,, AL 35124	510(k) NO: K011502 PHONE NO : 205-733-0901	DEVICE: CRYSTAL AND CRYSTAL-CARE IMPLANTS SYSTEM SE DECISION MADE: 22-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA

CSIST ATTN: CARL ALLETO 1100 LAKEVIEW BLVD. DENTION, TX 76208	510(k) NO: K012327 PHONE NO : 214-262-4209	DEVICE: CSIST DICOM GATEWAY/IMAGE MANAGER SE DECISION MADE: 20-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
CTI PET SYSTEMS, INC. ATTN: WILLIAM SKREMSKY 810 INNOVATION DR. KNOXVILLE, TN 37932-2571	510(k) NO: K013504 PHONE NO : 865-218-2522	DEVICE: MODIFICATION TO: ECAT LSO PET/CT SCANNER SE DECISION MADE: 31-OCT-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
CYBERCARE TECHNOLOGIES, INC. ATTN: GORDON J PETERS 7840 ROSWELL RD., BLDG. 300 SUITE 320 ATLANTA, GA 30350-4889	510(k) NO: K003485 PHONE NO : 770-352-9540	DEVICE: CARE PROVIDER STATION ADDITION OF WEIGHT SCALE SE DECISION MADE: 11-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
CYBERMED, INC. ATTN: GARY J ALLSEBROOK 16303 PANORAMIC WAY SAN LEANDRO, CA 94578-1116	510(k) NO: K013878 PHONE NO : 510-276-2648	DEVICE: CYBERMED, INC., V-WORKS SE DECISION MADE: 07-DEC-2001 510(k) SUMMARY AVAILABLE FROM FDA
CYCLOTEC ATTN: STEPHEN A MICHELSON 4871 NORTHWEST 65TH AVE. LAUDERHILL, FL 33319	510(k) NO: K010615 PHONE NO : 954-746-8330	DEVICE: CYCLOTEC AMT CTI TENS DEVICE SE DECISION MADE: 12-OCT-2001 510(k) STATEMENT
CYNOSURE, INC. ATTN: GEORGE CHO 10 ELIZABETH DR. CHELMSFORD, MA 01824	510(k) NO: K004039 PHONE NO : 978-256-4200	DEVICE: CYNOSURE PHOTOGENICA NEO-V SE DECISION MADE: 29-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
CYNOSURE, INC. ATTN: GEORGE CHO 10 ELIZABETH DR. CHELMSFORD, MA 01824	510(k) NO: K010005 PHONE NO : 978-256-4200	DEVICE: CYNOSURE PHOTOGENICA DL SE DECISION MADE: 02-APR-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

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

510(k) NO: K012790
PHONE NO : 978-256-4200

DEVICE: CYNOSURE PHOTOGENICA ER
SE DECISION MADE: 16-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012806
PHONE NO : 978-256-4200

DEVICE: CYNOSURE PHOTOGENICA VL
SE DECISION MADE: 19-NOV-2001
510(k) SUMMARY AVAILABLE FROM FDA

CYPRESS MEDICAL PRODUCTS, LTD.
ATTN: ANTONIO L GIACCIO
1202 SOUTH ROUTE 31
MCHENRY, IL 60050

510(k) NO: K012282
PHONE NO : 815-385-0100

DEVICE: STERILE POWDER FREE SYNTHETIC VINYL PATIENT EXAM GLOVE
SE DECISION MADE: 06-AUG-2001
510(k) STATEMENT

DADE BEHRING, , INC.
ATTN: CYNTHIA VAN DUKER
2040 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K010418
PHONE NO : 916-374-3105

DEVICE: DRIED GRAM-NEGATIVE AND GRAM-POSITIVE MIC/COMBO PANELS
SE DECISION MADE: 22-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, , INC.
ATTN: RADAMES RIESGO
13251 NW 9TH TERRACE
MIAMI, FL 33182

510(k) NO: K011235
PHONE NO : 305-480-7558

DEVICE: SYSMEX AUTOMATED COAGULATION ANALYZER / MODEL # CA-1500
SE DECISION MADE: 20-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
LLEGEN/EPINEPHRINE TEST CARTRIDE, DADE PFA COLLEAGEN /ADP
ATTN: RADAMES RIESGO
GLASGOW BUSINESS COMMUNITY;
BLDG. 500 MAIL BOX 514
P.O. BOX 6101, NEWARK, DE 19714-6101

510(k) NO: K002885
PHONE NO : 305-480-7558

DEVICE: DADE PFA-100 PLATELET FUNCTION ANALYZER MODEL-100, DADE PFA CC
SE DECISION MADE: 21-JUN-2001
510(k) SUMMARY AVAILABLE FROM FDA

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
GLASGOW BUSINESS COMMUNITY;
BLDG. 500 MAIL BOX 514
P.O. BOX 6101, NEWARK, DE 19714-6101

510(k) NO: K003501
PHONE NO : 302-631-6276

DEVICE: N PROTEIN STANDARD UY CALIBRATOR
SE DECISION MADE: 15-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: REBECCA S AYASH
GLASGOW BUSINESS COMMUNITY;
BLDG. 500 MAIL BOX 514
P.O. BOX 6101, NEWARK, DE 19714-6101

510(k) NO: K003503
PHONE NO : 302-631-6276

DEVICE: N LATEX CYSTATIN C
SE DECISION MADE: 13-MAR-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
, MODEL CBHOG, BHOG CALPAK,MODEL CBHOG-C, BHOG DILPAK, MOD
ATTN: LAURENCE A POTTER
RT. 896, GLASCOW BLDG. 500
NEWARK, DE 19714

510(k) NO: K003696
PHONE NO : 302-631-0441

DEVICE: STRATUS CS STAT FLUOROMETRIC ANALYZER BHOG TESTPAK,TEST SYSTEM
SE DECISION MADE: 25-JAN-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
GLASGOW BUSINESS COMMUNITY;
BLDG. 500 MAIL BOX 514
P.O. BOX 6101, NEWARK, DE 19714-6101

510(k) NO: K010061
PHONE NO : 302-631-6567

DEVICE: DIMENSION CLINICAL CHEMISTRY SYSTEM, MODEL XPAND
SE DECISION MADE: 14-MAR-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K010206
PHONE NO : 302-631-6567

DEVICE: DIMENSION ENZYMATIC CARBONATE (ECO2) FLEX METHOD, CATALOG DF13
SE DECISION MADE: 16-MAR-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

DADE BEHRING, INC.
ATTN: GEORGE PLUMMER
P.O. BOX 6101, BUILDING 500
NEWARK, DE 19714

510(k) NO: K010313
PHONE NO : 302-631-9798

DEVICE: DIMENSION CINI FLEX REAGENT CARTRIDGE
SE DECISION MADE: 20-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: GEORGE PLUMMER
P.O. BOX 6101, BUILDING 500
NEWARK, DE 19714

510(k) NO: K010314
PHONE NO : 302-631-9798

DEVICE: DIMENSION CINI CALIBRATOR
SE DECISION MADE: 20-APR-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: RADAMES RIESGO
P.O. BOX 6101
MAILING STATION 514
NEWARK,, DE 19714

510(k) NO: K010494
PHONE NO : 305-480-7558

DEVICE: SYSMEX AUTOMATED COAGULATION ANALYZER, MODEL CA-1500
SE DECISION MADE: 01-MAY-2001

510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: DONNA A WOLF
514 GBC DRIVE
NEWARK, DE 19702

510(k) NO: K010871
PHONE NO : 302-631-0384

DEVICE: TGL FLEX REAGENT CARTRIDGE
SE DECISION MADE: 09-JUL-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: RICHARD M VAUGHT
GLASGOW BUSINESS COMMUNITY
BLDG 500, MS 514 P.O.BOX 6101
NEWARK, DE 19714-6101

510(k) NO: K011033
PHONE NO : 302-631-6567

DEVICE: DIMENSION LITHIUM (LI) FLEX REAGENT CARTRIDGE, MODEL DF 132
SE DECISION MADE: 07-JUN-2001

510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: RICHARD M VAUGHT
GLASGOW BUSINESS COMMUNITY
BLDG 500, MS 514 P.O.BOX 6101
NEWARK, DE 19714-6101

510(k) NO: K011035
PHONE NO : 302-631-6567

DEVICE: DIMENSION DRUG CALIBRATOR, MODEL DC22B
SE DECISION MADE: 14-JUN-2001

510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: LORRAINE H PIESTRAK
P.O. BOX 6101 BUILDING 500
GLASGOW BUSINESS COMMUNITY
NEWARK,, DE 19714

510(k) NO: K011112
PHONE NO : 302-631-6279

DEVICE: CYCLOSPORINE CALIBRATOR
SE DECISION MADE: 17-JUL-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K011665
PHONE NO : 302-631-6276

DEVICE: BCT SYSTEM
SE DECISION MADE: 09-AUG-2001
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, INC.
ATTN: CATHY CRAFT
GLASGOW BUSINESS COMMUNITY
P.O. BOX 6101, BUILDING 500
NEWARK, DE 19714

510(k) NO: K011852
PHONE NO : 302-631-6280

DEVICE: DIMENSION HAIC ASSAY, MODEL DF105
SE DECISION MADE: 15-NOV-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
DADE BEHRING, INC. ATTN: REBECCA S AYASH GLASGOW SITE P.O. BOX 6101 NEWARK, DE 19714	510(k) NO: K013114 PHONE NO : 302-631-6276	DEVICE: BCS SYSTEM SE DECISION MADE: 09-NOV-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: K013126 PHONE NO : 302-631-6276	DEVICE: N LP(A) STANDARD SY SE DECISION MADE: 09-NOV-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: K013130 PHONE NO : 302-631-6276	DEVICE: N LP(A) CONTROL SY SE DECISION MADE: 18-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
DADE MICROSCAN, INC. ATTN: CYNTHIA VAN DUKER 1584 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K003619 PHONE NO : 916-374-3105	DEVICE: DRIED GRAM-POSITIVE MIC/COMBO PANELS SE DECISION MADE: 09-JAN-2001 510(k) SUMMARY AVAILABLE FROM FDA
DADE MICROSCAN, INC. ATTN: CYNTHIA VAN DUKER 1584 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K010159 PHONE NO : 916-374-3105	DEVICE: DRIED GRAM-NEGATIVE AND GRAM-POSITIVE MIC/COMBO PANELS SE DECISION MADE: 27-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
DADE MICROSCAN, INC. ATTN: CYNTHIA VAN DUKER 1584 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K013423 PHONE NO : 916-374-3105	DEVICE: MICROSCAN DRIED GRAM NEGATIVE OVERNIGHT MIC/COMBO PANELS SE DECISION MADE: 12-DEC-2001 510(k) STATEMENT
DALTON MEDICAL CORP. ATTN: WILL RIDGWAY 1103 VENTURE CT. CARROLLTON, TX 75006	510(k) NO: K010395 PHONE NO : 972-418-5129	DEVICE: E-POWER SE DECISION MADE: 11-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA

DAN MED, INC. ATTN: THOMAS SANDGAARD 4 WEST DRY CREEK CIRCLE, SUITE 260 DENVER, CO 80120	510(k) NO: K010745 PHONE NO : 800-495-6670	DEVICE: EMS 3000 SE DECISION MADE: 27-JUN-2001 510(k) STATEMENT
DAN MED, INC. ATTN: THOMAS SANDGAARD 4 WEST DRY CREEK CIRCLE, SUITE 260 DENVER, CO 80120	510(k) NO: K012885 PHONE NO : 800-495-6670	DEVICE: NEUROMOVE NM900 SE DECISION MADE: 08-NOV-2001 510(k) STATEMENT
DANISH DIAGNOSTIC DEVELOPMENT A/S ATTN: NIELS S ORENSEN DR. NEERGAARDSVEJ 5F 2970 HORSHOM,	510(k) NO: K011611 PHONE NO : 454 576 8888	DEVICE: CARDIOCAM MODEL 9CSY0799 SE DECISION MADE: 08-JUN-2001 510(k) STATEMENT
DANMAR PRODUCTS, INC. ATTN: KAREN A LINDNER 221 JACKSON INDUSTRIAL DR. ANN ARBOR, MI 48103	510(k) NO: K003630 PHONE NO : 734-761-1990	DEVICE: DANMAR PRODUCTS MICHIGAN CRANIAL HELMET SE DECISION MADE: 29-MAY-2001 510(k) SUMMARY AVAILABLE FROM FDA
DANVILLE MATERIALS, INC. ATTN: CRAIG R BRUNS 2021 OMEGA DR. SAN RAMON, CA 94583	510(k) NO: K012354 PHONE NO : 925-838-7940	DEVICE: SNOWPOST, SNOWLIGHT SE DECISION MADE: 10-OCT-2001 510(k) SUMMARY AVAILABLE FROM FDA
DATA CRITICAL CORP. ATTN: TERESA DAVIDSON 19820 NORTH CREEK PKWY., #100 BOTHELL, WA 98011	510(k) NO: K003998 PHONE NO : 425-482-7047	DEVICE: FLEXVIEW CLINICAL MONITORING SYSTEM SE DECISION MADE: 07-MAR-2001 510(k) SUMMARY AVAILABLE FROM FDA
DATA CRITICAL CORP. ATTN: TERESA DAVIDSON 19820 NORTH CREEK PKWY., #100 BOTHELL, WA 98011	510(k) NO: K010912 PHONE NO : 425-482-7047	DEVICE: ALARMVIEW WIRELESS DATA NETWORK SYSTEM SE DECISION MADE: 05-APR-2001 510(k) SUMMARY AVAILABLE FROM FDA
DATA CRITICAL CORP. ATTN: TERESA DAVIDSON 19820 NORTH CREEK PKWY., #100 BOTHELL, WA 98011	510(k) NO: K011999 PHONE NO : 425-482-7047	DEVICE: MODIFICATION TO FLEXVIEW CLINICAL MONITORING SYSTEM SE DECISION MADE: 24-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA
DATA CRITICAL CORP. ATTN: TERESA DAVIDSON 19820 NORTH CREEK PKWY., #100 BOTHELL, WA 98011	510(k) NO: K012005 PHONE NO : 425-482-7047	DEVICE: MODIFICATION TO ALARMVIEW WIRELESS DATA NETWORK SYSTEM SE DECISION MADE: 24-JUL-2001 510(k) SUMMARY AVAILABLE FROM FDA