

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 1

3M CO.
ATTN: STEPHAN NORSTED
5353 WAYZATA BLVD.
SUITE 505
MINNEAPOLIS, MN 55416

510(k) NO: K004009
PHONE NO : 952-946-8080

DEVICE: 3M ATTEST 290 AUTO-READER
SE DECISION MADE: 25-MAR-2002

510(k) SUMMARY AVAILABLE FROM FDA

3M ESPE AG DENTAL PRODUCTS
ATTN: ANDREAS PETERMANN
ESPE PLATZ
SEEFELD, BAVARIA,

510(k) NO: K020256
PHONE NO : 011 498 152700139

DEVICE: UNICEM
SE DECISION MADE: 25-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: LINDA MORRIS
1920 HURD MS 1-8
IRVING, TX 75038

510(k) NO: K012996
PHONE NO : 972-518-6711

DEVICE: BARBITURATES
SE DECISION MADE: 20-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: ALICIA SIMPSON
1920 HURD DR 8-21
IRVING, TX 75038

510(k) NO: K012998
PHONE NO : 972-518-7864

DEVICE: AMPHETAMINE/METHAMPHETAMINE
SE DECISION MADE: 13-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: ALICIA SIMPSON
1920 HURD DRIVE
IRVING, TX 75038

510(k) NO: K013001
PHONE NO : 972-518-7864

DEVICE: METHADONE
SE DECISION MADE: 20-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: ALICIA SIMPSON
1920 HURD DR 8-21
IRVING, TX 75038

510(k) NO: K013004
PHONE NO : 972-518-7864

DEVICE: COCAINE
SE DECISION MADE: 13-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: LINDA MORRIS
1920 HURD DRIVE
IRVING, TX 75038

510(k) NO: K013096
PHONE NO : 972-518-6711

DEVICE: PHENCYCLIDINE
SE DECISION MADE: 13-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: LINDA MORRIS
1920 HURD DRIVE
IRVING, TX 75038

510(k) NO: K013100
PHONE NO : 972-518-6711

DEVICE: PROPOXYPHENE
SE DECISION MADE: 20-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ABBOTT LABORATORIES
ATTN: LINDA MORRIS
1920 HURD
IRVING, TX 75062

510(k) NO: K013143
PHONE NO : 972-518-6711

DEVICE: BENZODIAZEPINES
SE DECISION MADE: 13-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 2

ABBOTT LABORATORIES ATTN: LINDA MORRIS 1920 HURD IRVING, TX 75062	510(k) NO: K013247 PHONE NO : 972-518-6711	DEVICE: CANNABINOIDS SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ABBOTT LABORATORIES ATTN: ALICIA SIMPSON 1920 HURD DRIVE IRVING, TX 75038	510(k) NO: K013314 PHONE NO : 972-518-7864	DEVICE: OPIATES SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ACIST MEDICAL SYSTEMS, INC. ATTN: CARL M BEAURLINE 7450 FLYING CLOUDS DR. SUITE 150 EDEN PRAIRIE, MN 55344	510(k) NO: K012983 PHONE NO : 612-995-9319	DEVICE: ACIST 4 FRENCH ANGIOGRAPHIC CATHETER SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ADVEN MEDICAL ATTN: MARK W ALDANA 1001 SLATON HWY. LUBBOCK, TX 79404	510(k) NO: K013987 PHONE NO : 806-745-7718	DEVICE: REPROCESSED DISPOSABLE TROCARS SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILALE FROM FDA
AESCULAP, INC. ATTN: JOYCE THOMAS 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K011030 PHONE NO : 800-258-1946	DEVICE: AESCULAP -MIETHKE SHUNT SYSTEM SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: GEORG KELLER 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K014149 PHONE NO : 800-258-1946	DEVICE: PAEDISCOPE, MODEL # P010A AND PF011A SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K014172 PHONE NO : 610-258-1946	DEVICE: NELSON ELECTROSURGICAL UNIT, MODEL GN640 SE DECISION MADE: 19-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: LISA MILLINGTON 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K014207 PHONE NO : 800-258-1946	DEVICE: REPOSABLE INSTRUMENT SYSTEM, MODELS MF001-MF083 SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AIRSEP CORP. ATTN: CHARLOTTE H HAMILTON 290 CREEKSIDE DR. BUFFALO, NY 14228-2070	510(k) NO: K020324 PHONE NO : 716-691-0202	DEVICE: LIFESTYLE OXYGEN CONCENTRATOR SE DECISION MADE: 13-MAR-2002 510(k) STATEMENT

AKSYS, LTD. TMENT KIT-1W605,PHD HARD PLUMBING ATTN: JAN L ZORN TWO MARRIOTT DRIVE LINCOLNSHIRE, IL 60069	510(k) NO: K010131 KIT-1W604, PHD BLOOD TUB PHONE NO : 847-229-2020	DEVICE: PHD PERSONAL HEMODIALYSIS INSTRUMENT-1M101, PHD WATER PRE-TREA SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AKTINA MEDICAL PHYSICS CORP. ATTN: JOAN KACHAROPOULOS 360 NORTH ROUTE 9W CONGERS, NY 10920	510(k) NO: K014081 PHONE NO : 845-268-0101	DEVICE: AKTINA MEDICAL PHYSICS RADIATION THERAPY WEDGES SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ALLEGIANCE HEALTHCARE CORP. ATTN: SHARON ROBBINS 1500 WAUKEGAN RD. MPWM-1E MOGAW PARK, IL 60085	510(k) NO: K020593 PHONE NO : 847-785-3311	DEVICE: CONVERTORS SMS POLYOLEFIN GOWN SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ALUM CREEK WHEELCHAIR CO., INC. ATTN: RICHARD ROY 393 EAST TOWN STREET COLUMBUS, OH 43215	510(k) NO: K020536 PHONE NO : 614-221-1010	DEVICE: GAZELLE WHEELCHAIR SE DECISION MADE: 15-MAR-2002 510(k) STATEMENT
AMERICAN BIO MEDICA CORP. ATTN: HENRY WELLS 9110 RED BRANCH ROAD COLUMBIA, MD 21045	510(k) NO: K014101 PHONE NO : 410-992-4734	DEVICE: RAPIDONE-OXY TEST SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN DIAGNOSTICA, INC. ATTN: JOHN B BERRYMAN 222 RAILROAD AVE. GREENWICH, CT 06830	510(k) NO: K013168 PHONE NO : 203-661-0000	DEVICE: IMUBIND PLASMA PAI-1 ELISA,MODEL 822 SE DECISION MADE: 07-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN DIAGNOSTICA, INC. ATTN: JOHN BERRYMAN 222 RAILROAD AVE. GREENWICH, CT 06830	510(k) NO: K013318 PHONE NO : 203-661-0000	DEVICE: ACTICHROME HEPARIN (ANTI-FXA), MODEL 832 SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN DIAGNOSTICA, INC. ATTN: JOHN B BERRYMAN 222 RAILROAD AVE. GREENWICH, CT 06830	510(k) NO: K013492 PHONE NO : 203-661-0000	DEVICE: IMUBIND TPA ELISA, MODEL 860 SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN MEDICAL SYSTEMS, INC. ATTN: ELSA A LINKE 10700 BREN RD., WEST MINNETONKA, MN 55343	510(k) NO: K020446 PHONE NO : 952-930-6309	DEVICE: MODIFICATION TO STRAIGHT-IN BONE SCREW FIXATION SYSTEM SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

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FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 4

AMERICAN MEDICAL SYSTEMS, INC. ATTN: MARK MCINIVRE 10700 BREN RD., WEST MINNETONKA, MN 55343	510(k) NO: K020663 PHONE NO : 952-930-6120	DEVICE: MODIFICATION TO SPARC SLING SYSTEM SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AMLUCK, INC. /AK-4000 ATTN: YANG TIEN-HSING NO. 58, FU-CHIUN ST. NSIN-CHU CITY,	510(k) NO: K012796 PHONE NO : 886 352 08829	DEVICE: AMLUCK AUTOMATIC DIGITAL WRIST, BLOOD PRESSURE MONITOR AK-3000 SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ANGIPLAST PRIVATE LTD. ATTN: ASHIT B SHAH 4803, PHASE IV, G.I.D.C., VATVA AHMEDABAD,	510(k) NO: K012189 PHONE NO : 917 958 50661	DEVICE: ANGELTOUCH VENTED IV ADMINISTRATION SET SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AR ALLIANCE HEALTHCARE SDN. BHD. ATTN: CHUA CHOON CHUAN 8, LORONG INDUSTRI 11, KAWASAN PERINDUSTRIAN BUKIT PANCHOR, NIBONG TEBAL, PULAU PINANG,	510(k) NO: K020359 PHONE NO : 60 04 5937616	DEVICE: ULTRA TOUCH POWDERED LATEX EXAMINATION GLOVES SE DECISION MADE: 06-MAR-2002 510(k) STATEMENT
ARMKEL LLC ATTN: STEPHEN C KOLAKOWSKY P.O. BOX 1001 HALF ACRE RD CRANEURY,, NJ 08512	510(k) NO: K013433 PHONE NO : 609-655-6308	DEVICE: TROJAN PASSION BERRY GEL SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: ANN WATERHOUSE 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K014155 PHONE NO : 941-643-5553	DEVICE: OPENING/CLOSING WEDGE OSTETOMY PLATES SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ARTHROCARE CORP. ATTN: BRUCE PROTHRO 680 VAQUEROS AVENUE SUNNYVALE, CA 94085	510(k) NO: K014290 PHONE NO : 408-736-0224	DEVICE: ENTEC PLASMA WANDS SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ARTHROCARE CORP. ORD; WANDS ATTN: BRUCE PROTHRO 680 VAQUEROS AVE. SUNNYVALE, CA 94085	510(k) NO: K020557 PHONE NO : 408-736-0224	DEVICE: ARTHROCARE CONTROLLER; ARTHROCARE CABLE; FOOT CONTROL; POWER C SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ARTHROCARE CORP. ORD; WANDS ATTN: VALERIE DEFIESTA-NG 680 VAQUEROS AVE. SUNNYVALE, CA 94085	510(k) NO: K020621 PHONE NO : 408-736-0224	DEVICE: ARTHROCARE CONTROLLER; ARTHROCARE CABLE; FOOT CONTROL; POWER C SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

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FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 5

ARTHCARE CORP. ; FOOT CONTROL; POWER CORD; AND WANDS ATTN: VALERIE DEFIESTA-NG 680 VAQUEROS AVE. SUNNYVALE, CA 94085	510(k) NO: K020622 PHONE NO : 408-736-0224	DEVICE: ARTHROCARE CONTROLLER (SYSTEM 2000 AND 8000); ARTHROCARE CABLE SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ARTHROTEK, INC. ATTN: SARA B SHULTZ P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K014305 PHONE NO : 219-267-6639	DEVICE: RESORBABLE LACTOSORB-L ACL CROSSPIN SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ASCLEPION-MEDITEC AG ATTN: WILLIAM KELLEY 23832 VIA MONIE COTO DE CAZA, CA 92708	510(k) NO: K014057 PHONE NO :	DEVICE: DERMASTAR ER:YAG LASER SYSTEM SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ASEPTICO, INC. LE: AHP-88MP 8:1 REDUCTION CONTRANGLE - PUSH BUTTON ATTN: GRANT RAMALEY 8333 216TH ST., S.E. WOODINVILLE, WA 98072	510(k) NO: K020137 PHONE NO : 425-487-3157	DEVICE: AHP-66 4:1 REDUCTION CONTRANGLE: AHP-88 8:1 REDUCTION CONTRANG SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AXIS-SHIELD DIAGNOSTICS, LTD. ATTN: EILEEN MCCAFFERTY THE TECHNOLOGY PARK LUNA PLACE DUNDEE, SCOTLAND,	510(k) NO: K020156 PHONE NO : 00 44 1382422000	DEVICE: DIASTAT TOTAL ANTI-CARDIOLIPIN, MODEL FCAR 100T SE DECISION MADE: 06-MAR-2002 510(k) STATEMENT
BAXTER HEALTHCARE CORP. ATTN: MARY KONROWSKI RT. 120 & WILSON RD. ROUND LAKE, IL 60073	510(k) NO: K020485 PHONE NO : 847-270-5619	DEVICE: ALL-IN-ONE TWO CHAMBER CONTAINER 3200 ML, 2000 ML & 1000 ML SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYER CORP. ATTN: THOMAS F FLYNN 63 NORTH ST. MEDFIELD, MA 02052-1688	510(k) NO: K020806 PHONE NO : 508-359-3877	DEVICE: ACS:180 & ADVIA CENTAUR AFP IMMUNOASSAY SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYER DIAGNOSTICS CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE TARRYTOWN, NY 10591-5097	510(k) NO: K020217 PHONE NO : 914-524-2446	DEVICE: ACS:180 AND ADVIA CENTAUR IPTH IMMUNOASSAY SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYLIS MEDICAL CO., INC. 45 ATTN: KRIS SHAH 5160 EXPLORER DR. #33 MISSISSAUGA, ONTARIO,	510(k) NO: K014075 PHONE NO : 905 602 4875	DEVICE: BMC COAXIAL INJECTABLE CATHETER, MODEL CIC 38/145 AND CIC 35/1 SE DECISION MADE: 07-MAR-2002 510(k) STATEMENT

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FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 6

ED ATTN: PASQUALE AMOTO ONE BECTON DRIVE MC226 FRANKLIN LAKES, NJ 07417	510(k) NO: K020523 PHONE NO : 201-847-4513	DEVICE: ED BIFURCATED NEEDLE, MODELS 301754, 301755, 301756, 301757 SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: GAIL LEFEBVRE 200 SOUTH KRAEMER BLVD., W-104 P.O. BOX 8000 BREA, CA 92822-8000	510(k) NO: K020521 PHONE NO : 714-993-8503	DEVICE: MODIFICATION TO VIGIL LIPID CONTROL SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BECTON, DICKINSON AND COMPANY ATTN: BRADFORD M SPRING 7 LOVETON CIR. SPARKS, MD 21152-0999	510(k) NO: K020322 PHONE NO : 410-316-4206	DEVICE: ED PHOENIX AUTOMATED MICROBIOLOGY SYSTEM SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIO MEDI COM ATTN: COLLEEN DENSMORE 7992 CASTLEWAY DRIVE INDIANAPOLIS, IN 46250	510(k) NO: K020068 PHONE NO : 317-849-1916	DEVICE: SONOREAL 3D SYSTEM SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOGENEX LABORATORIES ATTN: GURVINDER S NANDA 4600 NORRIS CANYON RD. SAN RAMON, CA 94583	510(k) NO: K012960 PHONE NO : 925-543-1336	DEVICE: BIOGENEX MONOCLONAL ANTI-PROGESTERONE RECEPTOR SE DECISION MADE: 08-MAR-2002 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: K020645 PHONE NO : 205-967-7880	DEVICE: MODIFICATION TO THE MAESTRO SYSTEM SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOMERIEUX, INC. ATTN: NANCY WEAVER 595 ANGLUM DR. HAZELWOOD, MO 63042-2320	510(k) NO: K020871 PHONE NO : 314-731-8500	DEVICE: VITEK 2 ANTIMICROBIAL SUSCEPTIBILITY TEST SYSTEM FOR LEVOFLOX SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: PATRICIA S BERES P.O. BOX 587 WARSAW, IN 46581	510(k) NO: K020580 PHONE NO : 219-267-6639	DEVICE: X-SERIES BI-METRIC HIP FEMORAL COMPONENTS SE DECISION MADE: 22-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOVISION AG ATTN: DAVID S FERNQUIST 27 MAUCHLY, UNIT 206 IRVINE, CA 92618	510(k) NO: K014000 PHONE NO : 949-496-0897	DEVICE: VISTITOME 20-10 MICROKERATOME SE DECISION MADE: 11-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

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FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 7

BOSTON SCIENTIFIC CORP.
ATTN: MARK MURPHY
ONE SCIMED PLACE
MAPLE GROVE, MN 55311-1566

510(k) NO: K014195
PHONE NO : 763-494-2377

DEVICE: KAYAK HYDROPHILIC GUIDE WIRES
SE DECISION MADE: 19-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC, TARGET
ATTN: SETH A SCHULMAN
47900 BAYSIDE PARKWAY
FREMONT, CA 94538

510(k) NO: K014109
PHONE NO : 510-440-7753

DEVICE: IN-TIME RETRIEVAL DEVICE
SE DECISION MADE: 12-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BRAINLAB AG
ATTN: STEFAN VILSMEIER
AMMERHALSTRASSE 8
HELMSTETTEN,

510(k) NO: K004022
PHONE NO : 498 999 16680

DEVICE: M3 (MIRCO-MULTILEAF COLLIMATOR
SE DECISION MADE: 26-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BRAINLAB AG
ATTN: RAINER BIRKENBACH
AMMERHALSTRASSE 8
HELMSTETTEN,

510(k) NO: K012448
PHONE NO : 49 89 99166800

DEVICE: VECTORVISION TRAUMA
SE DECISION MADE: 14-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BRIGHWAY GLOVES PVT. LTD.
ATTN: N. PARAMASIVAN
PIONEER MANIKANDAN BUILDINGS
VADASERY, NAGAR COIL
TAMIL NADU,

510(k) NO: K014279
PHONE NO : 91 465 2276291

DEVICE: LATEX EXAMINATION GLOVES (POWDER FREE)
SE DECISION MADE: 20-MAR-2002

510(k) SUMMARY AVAILABLE FROM FDA

BRIGHWAY GLOVES PVT. LTD.
ATTN: N. PARAMASIVAN
PIONEER MANIKANDAN BUILDINGS
VADASERY, NAGAR COIL
TAMIL NADU,

510(k) NO: K014280
PHONE NO : 91 465 2276291

DEVICE: LATEX EXAMINATION GLOVE (POWDERED)
SE DECISION MADE: 20-MAR-2002

510(k) SUMMARY AVAILABLE FROM FDA

BYPASS LTD.
ATTN: JONATHAN S KAHAN
555 THIRTEENTH STREET NW
WASHINGTON, DC 20004-1109

510(k) NO: K020470
PHONE NO : 202-637-5794

DEVICE: MODIFICATION TO CORLINK AUTOMATED ANASTOMOTIC DEVICE
SE DECISION MADE: 08-MAR-2002

510(k) SUMMARY AVAILABLE FROM FDA

CANADIAN THEATRE PRODUCTS LTD.
ATTN: ANN-MARIE O'KEEFE
#210-828 HARBOUSIDE DRIVE
NORTH VANCOUVER, B.C.,

510(k) NO: K020702
PHONE NO : 604 904 9577

DEVICE: O'REGAN DISPOSABLE ANOSCOPE
SE DECISION MADE: 29-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CARDIAC ASSIST DEVICES, INC.
OE
ATTN: RASSOLL RASHIDI
11000 CEDAR AVE., SUITE 451
CLEVELAND, OH 44106-3052

510(k) NO: K012520
PHONE NO : 216-791-2234

DEVICE: GYRO-TIP LARIAT DEFLECTABLE LOOP MAPPING CATHETER, MODEL GTL-2
SE DECISION MADE: 27-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 8

CARDIOFOCUS, INC. ATTN: JOHN GREENBAUM 20310 SW 48TH STREET FT. LAUDERDALE, FL 33332	510(k) NO: K013201 PHONE NO : 954-680-2548	DEVICE: CARDIOFOCUS DIODE LASER SYSTEM, MODELS 60R, 60NR, 30NR SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CARE REHAB, INC. ATTN: CHRISTIAN HUNT 1124 DOMINION COURT MCLEAN, VA 22102	510(k) NO: K020437 PHONE NO : 703-448-9644	DEVICE: CLASSIC TENS SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CHASE MEDICAL, INC. ATTN: DAVE HERNON 1710 FIRMAN DRIVE SUITE 100 RICHARDSON, TX 75081	510(k) NO: K020233 PHONE NO : 972-783-0644	DEVICE: CHASE CARDIOVASCULAR PATCH KIT SE DECISION MADE: 14-MAR-2002 510(k) STATEMENT
CHESHIRE DIAGNOSTICS LTD. ATTN: NEIL B STRINGER MANAGEMENT CENTRE, INWARD WAY ELLESMERE PORT CHESHIRE,	510(k) NO: K020241 PHONE NO : 44 151 3488023	DEVICE: QACA IGG/IGM ELISA KIT SE DECISION MADE: 13-MAR-2002 510(k) STATEMENT
CHURCHILL MEDICAL SYSTEMS, INC. ATTN: KETH PALUCH 87 VENTURE DR. DOVER, NH 03820	510(k) NO: K013949 PHONE NO : 603-743-5988	DEVICE: UNIVERSAL VIAL ACCESS SPIKE WITH NEEDLELESS CONNECTOR SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CHURCHILL MEDICAL SYSTEMS, INC. ON SET 19 GA, SHS1900 SERIES; WING SAFE INFUSION SET 22 GA ATTN: KEITH PALUCH 87 VENTURE DR. DOVER, NH 03820	510(k) NO: K020544 PHONE NO : 603-743-5988	DEVICE: WING SAFE INFUSION SET 20 GA, SHS2000 SERIES; WING SAFE INFUSI SE DECISION MADE: 12-MAR-2002 510(k) STATEMENT
CLINICON CORP. ORIES ATTN: SEAN M CURRY 16787 BERNARDO CENTER DRIVE SUITE A SAN DIEGO, CA 92128	510(k) NO: K014236 PHONE NO : 858-675-8200	DEVICE: CLINICON WAVEGUIDE PLATFORM WITH INTERCONNECT FOR LUXAR ACCESS SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COAPT SYSTEMS, INC. ATTN: JUDE PAGANELLI 261 HAMILTON AVENUE SUITE 413 PALO ALTO, CA 94301	510(k) NO: K014153 PHONE NO : 650-289-1010	DEVICE: COAPT SYSTEMS ENDOTINE DEVICE SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

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FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 9

CODAN US CORP. ATTN: MARILYN R POURAZAR 3511 WEST SUNFLOWER AVE. SANTA ANA, CA 92704-6944	510(k) NO: K013714 PHONE NO : 800-332-6326	DEVICE: CODAN US I.V. ADMINISTRATION SET, MODEL B400 SP SE DECISION MADE: 28-MAR-2002 510(k) STATEMENT
CODMAN & SHURILEFF, INC. ATTN: ELIZABETH DOLAN 325 PARAMOUNT DR. RAYNHAM, MA 02767-0350	510(k) NO: K020667 PHONE NO : 508-828-3262	DEVICE: CODMAN HAKIM SHUNT SYSTEMS SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COMFORT ORTHOPEDIC CO. LTD. ATTN: ERIC LEE NO. 120 NAN SHIANG TSUEN, SHOEI SHANG SHIANG HSIANG, CHIA-YI,	510(k) NO: K020451 PHONE NO : 886 5 2890303	DEVICE: COMFORT WHEELCHAIRS SE DECISION MADE: 14-MAR-2002 510(k) STATEMENT
COMPUTER MOTION, INC. ATTN: DAVID U THOMAS 130 CREMONA DRIVE, SUITE B GOLETA, CA 93117	510(k) NO: K013551 PHONE NO : 805-968-9600	DEVICE: ZEUS MICROWRIST ROBOTIC SURGICAL SYSTEM SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CONCEPTION TECHNOLOGIES ATTN: GRACE HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K020490 PHONE NO : 949-262-0411	DEVICE: PBS, PBSW WITH CATIONS AND PHENOL RED SE DECISION MADE: 28-MAR-2002 510(k) STATEMENT
CONSOLIDATED TECHNOLOGY ATTN: CANDICE BETZ 4401 FREDRICH LANE BLDG 1 SUITE 100 AUSTIN, TX 78744-1832	510(k) NO: K020237 PHONE NO : 512-445-5100	DEVICE: IMMUNOASSAY PLUS CONTROL, LEVELS 1, 2, AND 3 SE DECISION MADE: 19-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COOLTOUCH CORP. ATTN: DONALD V JOHNSON 9085 FOOTHILLS BOULEVARD ROSEVILLE, CA 95747	510(k) NO: K014035 PHONE NO : 916-677-1912	DEVICE: "COOLTOUCH" AND "COOLTOUCH-II" ND:YAG LASER SYSTEMS SE DECISION MADE: 07-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. GEOGRAPHIC VESSEL DILATOR; MODELS ATTN: KAREN WILK 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K020316 466-P306AU & 466-P306BU PHONE NO : 908-412-7446	DEVICE: CORDIS TRAPEASE PERMANENT VENA CAVA FILTER WITH THE VISEASE AN SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS NEUROVASCULAR, INC. RE-SHAPED TIPS ATTN: MARITZA CELAYA 14000 N.W. 57TH CT. MIAMI LAKES, FL 33014	510(k) NO: K020680 PHONE NO : 786-313-6546	DEVICE: PROWLER SELECT 10 AND 14 INFUSION CATHETERS WITH AND WITHOUT P SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 10

CORIN U.S.A. ATTN: JOEL BATTS 10500 UNIVERSITY CENTER DR., SUITE 190 TAMPA, FL 33612	510(k) NO: K012377 PHONE NO : 813-977-4469	DEVICE: OXFORD MODULAR SHOULDER PROSTHESIS, 192.XXX CATALOGUE SERIES SE DECISION MADE: 11-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COSMED S.R.L. ATTN: ROBERT SCHIFF 1129 BLOOMFIELD AVENUE WEST CALDWELL, NJ 07006	510(k) NO: K014262 PHONE NO : 973-227-1830	DEVICE: COSMED QUARK C12/QUARK T12 SE DECISION MADE: 26-MAR-2002 510(k) STATEMENT
CURASAN AG ATTN: THOMAS ARROWSMITH-LOWE 5 EAGLE CREEK ROAD P.O. BOX 3148 RUIDOSO, NM 88355	510(k) NO: K014156 PHONE NO : 505-336-7821	DEVICE: CERASORB ORTHO SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CURON MEDICAL, INC. ATTN: JONATHAN S KAHAN 555 THIRTEENTH STREET, N.W. WASHINGTON,, DC 20004-1109	510(k) NO: K014216 PHONE NO : 202-637-5794	DEVICE: SECCA SYSTEM SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: MAUREEN MENDE 2040 ENTERPRISE BOULEVARD WEST SACRAMENTO, CA 95691	510(k) NO: K020142 PHONE NO : 916-374-3174	DEVICE: RAPID/S PLUS GRAM-NEGATIVE MIC/COMBO PANELS SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: CYNTHIA VAN DUKER 2040 ENTERPRISE BOULEVARD WEST SACRAMENTO, CA 95691	510(k) NO: K020160 PHONE NO : 916-374-3105	DEVICE: DRIED GRAM-POSITIVE MIC/COMBO PANELS WITH AMPICILLIN SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: CYNTHIA VAN DUKER 2040 ENTERPRISE BOULEVARD WEST SACRAMENTO, CA 95691	510(k) NO: K020162 PHONE NO : 916-374-3105	DEVICE: DRIED GRAM-POSITIVE MIC/COMBO PANELS WITH PENICILLIN SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. MEIHOPRIM/SULFAMETHOXAZOLE ATTN: MAUREEN MENDE 1584 ENTERPRISE BOULEVARD WEST SACRAMENTO, CA 95691	510(k) NO: K020248 PHONE NO : 916-374-3174	DEVICE: MICROSCAN RAPID/S PLUS GRAM-NEGATIVE MIC/COMBO PANELS WITH TRI SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: KATHLEEN A DRAY-LYONS GLASGOW SITE P.O. BOX 6101 NEWARK, DE 19714	510(k) NO: K020441 PHONE NO : 781-826-4551	DEVICE: EMIT II PLUS MONOCLONAL COCAINE METABOLITE ASSAY SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 11

DADE MICROSCAN, INC. ATTN: CYNTHIA VAN DUKER 1584 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K020037 PHONE NO : 916-374-3105	DEVICE: DRIED GRAM NEGATIVE MIC/COMBO PANELS SE DECISION MADE: 22-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE MICROSCAN, INC. ERACILLIN (1.4, 4.4 - 256/4 UG/ML ATTN: MAUREEN MENDE 1584 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K020511 PHONE NO : 916-374-3174	DEVICE: MICROSCAN RADID/S PLUS GRAM-NEGATIVE MIC/COMBO PANELS WITH PIP SE DECISION MADE: 06-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DATEX-OHMEDA AND ACCESSORIES ATTN: JOEL C KENT 86 PILGRIM ROAD NEEDHAM, MA 02492	510(k) NO: K020479 PHONE NO : 781-449-8685	DEVICE: DATEX-OHMEDA S/5 NELLCOR COMPATIBLE SATURATION MODULE, M-NSAT SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DAVLITE TECHNOLOGIES ATTN: DAVID A MCNALLY 37 KRIS ALLEN DRIVE HOLDEN, MA 01520	510(k) NO: K020310 PHONE NO : 508-829-4602	DEVICE: DAVLITE MICROENDOSCOPE & ACCESSORIES SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DENKA SEIKEN'S ATTN: KEVIN MANGAN 3-4-2 NIHONBASHI KAYABACHO, CHUO-KU TOKYO,	510(k) NO: K011400 PHONE NO : 813 366 00421	DEVICE: MRSA-SCREEN SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DENKA SEIKEN'S ATTN: YOUSUKE MEGURO 3-4-2 NIHONBASHI KAYABACHO, CHUO-KU TOKYO,	510(k) NO: K013359 PHONE NO : 03 366 99421	DEVICE: LP(A)-LATEX SEIKEN ASSAY KIT SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DENTSPLY INIL. ATTN: P. JEFFERY LEHN 570 WEST COLLEGE AVE YORK, PA 17404	510(k) NO: K014188 PHONE NO : 717-845-7511	DEVICE: NEW PROPHY POWDER SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DEPUY ACROMED ATTN: KAREN F JURCZAK 325 PARAMOUNT DR. RAYNHAM, MA 02767	510(k) NO: K014053 PHONE NO : 508-828-3704	DEVICE: CONDUIT TCP GRANULES SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DEPUY ACROMED ATTN: KAREN F JURCZAK 325 PARAMOUNT DR. RAYNHAM, MA 02767	510(k) NO: K020522 PHONE NO : 508-828-3704	DEVICE: MODIFICATION TO SURGICAL TITANIUM MESH SYSTEM SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 12

DIAGNOSTIC PRODUCTS CORP. ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K013984 PHONE NO : 310-645-8200	DEVICE: IMMULITE BR-MA, MODEL #LKBR; IMMULITE 2000 BR-MA, MODEL #L2KBR SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTIC SYSTEMS LABORATORIES, ATTN: CARROLL POTTS 445 MEDICAL CENTER BLVD. WEBSTER, TX 77598	510(k) NO: K020128 PHONE NO : 281-332-9678	DEVICE: ACTIVE FREE BETA-HCG ELISA, MODEL DSL-10-8500 SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIAMOND DIAGNOSTICS, INC. ATTN: LINDA STUNDINER 331 FISKE STREET HOLLISTON, MA 01746	510(k) NO: K020596 PHONE NO : 508-429-0450	DEVICE: CALIBRATING MATERIAL, CAL-PAK, CAL & SLOPE STANDARDS SE DECISION MADE: 23-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIASORIN, INC. ATTN: DAVID IKEDA 1951 NORTHWESTERN AVE. P.O. BOX 285 STILLWATER, MN 55082-0285	510(k) NO: K014030 PHONE NO : 651-351-5592	DEVICE: 1,25-DIHYDROXYVITAMIN D125I RIA SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DISC-O-TECH MEDICAL TECHNOLOGIES, ATTN: JONATHAN S KAHAN 555 THIRTEENTH STREET, NW WASHINGTON, DC 20004	510(k) NO: K014072 PHONE NO : 202-637-5794	DEVICE: FIXION UNIPOLAR MODULAR HEMI-HIP SYSTEM (FIXION UH) SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DOCTOR'S RESEARCH GROUP, INC. ATTN: RICHARD DESLAURIERS 143 WOLCOTT RD. WOLCOTT, CT 06716	510(k) NO: K012535 PHONE NO : 203-879-9422	DEVICE: DRG DISPOSABLE VAGINAL SPECULUM SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DOLPHIN MEDICAL INC. ATTN: BILL CURNAN 9433 S. MORNING GLORY LANE HIGHLANDS RANCH, CO 80130	510(k) NO: K012989 PHONE NO : 720-348-0389	DEVICE: DOLPHIN 2000 OXIMETRY SENSOR, MODELS, 2050, 2351, 2354, 2070 SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DCN WILSON/WILSON-COOK MEDICAL, ATTN: MARGARET J POSNER 4900 BETHANAJA STATION RD. WINSTON-SALEM, NC 27105	510(k) NO: K020526 PHONE NO : 800-245-4717	DEVICE: MODIFICATION TO WILSON-COOK MULTIPLE BAND LIGATOR SE DECISION MADE: 19-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
DYNAREX CORP. ATTN: JOHN GAGLIARDI 7736 WOODSIDE COURT MAINEVILLE, OH 45039	510(k) NO: K012957 PHONE NO : 513-573-0085	DEVICE: TOWEL DRAPE, MODELS 4409, 4410 SE DECISION MADE: 06-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 13

EASTMAN KODAK COMPANY VIEW CR 900 SYSTEM, CATALOG# 1170976 ATTN: SUSAN PATE 343 STATE ST. ROCHESTER, NY 14650	510(k) NO: K020635 PHONE NO : 585-781-6314	DEVICE: KODAK DIRECTVIEW CR 800 SYSTEM, CATALOG# 1268622; KODAK DIRECT SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: FREDERIC TESTA 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K014276 PHONE NO : 973-299-9300	DEVICE: MODIFICATION TO EBI XFIX DFS SYSTEM SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: PATRICIA FLOOD 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K020403 PHONE NO : 973-299-9300	DEVICE: MODIFICATION TO EBI XFIX DFS OPTIROM ELBOW FIXATOR SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
EDWARDS LIFESCIENCES, LLC. ON MATERIAL ATTN: JASON SMITH ONE EDWARDS WAY IRVINE, CA 92614-5686	510(k) NO: K014052 PHONE NO : 949-250-2662	DEVICE: EDWARDS LIFESCIENCES PERCUTANEOUS SHEATH INTRODUCERS WITH OLIG SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
EDWARDS LIFESCIENCES, LLC. MATERIAL ATTN: JASON SMITH ONE EDWARDS WAY IRVINE, CA 92614-5686	510(k) NO: K014054 PHONE NO : 949-250-2662	DEVICE: EDWARDS LIFESCIENCES SWAN-GANZ MONITORING CATHETER WITH OLIGON SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENDIUS, INC. ATTN: GENE DIPOTO 23 WEST BACON ST. PLAINVILLE, MA 02762	510(k) NO: K014090 PHONE NO : 508-643-0983	DEVICE: ENDIUS SPINAL FIXATION SYSTEM SE DECISION MADE: 11-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENDO SURGICAL DEVICES, INC. ATTN: DEBBIE IAMPIETRO 7 TIFFANY TRAIL HOPKINION, MA 01748	510(k) NO: K013680 PHONE NO : 508-435-9893	DEVICE: CARBODISSECTING ENDOSCOPE SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENGINEERED MEDICAL SYSTEMS ATTN: PAUL DRYDEN 6329 W. WATERVIEW CT. MCCORDSVILLE, IN 46055	510(k) NO: K013089 PHONE NO : 317-335-3780	DEVICE: EMS HEPA FILTER AND HME COMBINATIONS SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENGINEERED MEDICAL SYSTEMS ATTN: PAUL DRYDEN 6329 W. WATERVIEW CT. MCCORDSVILLE, IN 46055-9501	510(k) NO: K013123 PHONE NO : 317-335-3780	DEVICE: EMS PULMONARY FUNCTION TESTING FILTER SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 14

ERADLINK, INC. ATTN: ALBERT J KOUBA 19529 CHAPARRAL CIR. PENN VALLEY, CA 95946-9443	510(k) NO: K020243 PHONE NO : 530-432-3791	DEVICE: LASERPRO 16 SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ETHICON ENDO-SURGERY, INC. ATTN: ELIZABETH MILLER 4545 CREEK RD. CINCINNATI, OH 45242-2839	510(k) NO: K020428 PHONE NO : 513-337-7146	DEVICE: ENDOPATH DILATING TIP TROCAR, MODEL #512XD SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
FIM MEDICAL ATTN: ERIC DEREI 30 RUE CAMILLE LYON,	510(k) NO: K010761 PHONE NO : 33 4 72348989	DEVICE: SPL-50 SPIROLYSER SE DECISION MADE: 05-MAR-2002 510(k) STATEMENT
FORINE MEDICAL INSTRUMENT CORP. ATTN: ABE WANG 12-9, LIN 5, MAO-CHANG VILLAGE SAN-CHIH HSIANG, TAIPEI HSIEN,	510(k) NO: K014002 PHONE NO : 886 226 360845	DEVICE: ALL SILICONE SUPRA-PUBIA CATHETER, MODELS 4880/4890 SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
FRIADENT GMBH ATTN: CAROL PATTERSON 21911 ERIE LANE LAKE FOREST, CA 92630	510(k) NO: K013867 PHONE NO : 949-462-0900	DEVICE: XIVE DENTAL IMPLANT SYSTEM SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GC AMERICA, INC. ATTN: TERRY L JORITZ 3737 WEST 127TH ST. ALSIP, IL 60803	510(k) NO: K020342 PHONE NO : 708-926-3105	DEVICE: UNIFIL FLOW SE DECISION MADE: 28-MAR-2002 510(k) STATEMENT
GE MEDICAL SYSTEMS ATTN: LARRY A KROGER P.O. BOX 414 MILWAUKEE, WI 53201	510(k) NO: K020796 PHONE NO : 262-544-3894	DEVICE: CARD IQ ANALYSIS II SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GE MEDICAL SYSTEMS INFORMATION ATTN: THOMAS J ENGLISH 4502 WOODLAND CORP.BLVD. TAMPA, FL 33614	510(k) NO: K012915 PHONE NO : 813-887-2107	DEVICE: DINAMAP PRO 1000 MONITOR, MODEL 1000 SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GEISTLICH-PHARMA ATTN: PETER S REICHERTZ 1050 CONNECTICUT AVE. N.W. WASHINGTON, DC 20036	510(k) NO: K014289 PHONE NO : 202-857-6378	DEVICE: ORTHOSS RESORBABLE BONE VOID FILLER SE DECISION MADE: 28-MAR-2002 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 15

GENERAL ELECTRIC MEDICAL SYSTEMS ATTN: DIANA M THORSON 15222 DEL AMO AVENUE TUSTIN, CA 92780	510(k) NO: K020524 PHONE NO : 800-888-0077	DEVICE: PATIENTNET MONITORING SYSTEM SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GETTINGE/CASTLE, INC. ATTN: FREDERICK R CATT 1777 EAST HENRIETTA RD. ROCHESTER, NY 14623-3133	510(k) NO: K020590 PHONE NO : 716-272-5013	DEVICE: MODEL 733HC GRAVITY/VACUUM STEAM STERILIZER SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GIMMI GMBH XXX.XX, ZXXX.XX,S.XXXX.XX, K0142.25 ATTN: DAGMAR MASER AMSTEL 320-I AMSTERDAM,	510(k) NO: K012869 PHONE NO : 312 042 89591	DEVICE: GIMMI ALPHA HYSTEROSCOPES & ACCESSORIES, MODELS E.8XXX.XX, T.8 SE DECISION MADE: 11-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GUIDANT CORP. YDROCOAT HYDROPHILIC COATING ATTN: JENNIFER PAE RIGGS 26531 YNEZ RD. TEMECULA, CA 92591-4628	510(k) NO: K020340 PHONE NO : 909-914-4581	DEVICE: MODIFICATION TO HI-TORQUE WHISPER LS AND MS GUIDE WIRES WITH H SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILAABLE FROM FDA
GYRUS ENT L.L.C. ATTN: GREGORY SREDIN 2925 APPLING RD BARTLETT, TN 38133	510(k) NO: K020594 PHONE NO : 901-373-0200	DEVICE: DIEGO POWERED DISSECTOR AND DRILL SYSTEM SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
H & A CONSULTANTS ATTN: SCOTT HENDERSON 2584 SADDLEWOOD LANE PALM HARBOR, FL 34685	510(k) NO: K020265 PHONE NO : 727-773-0414	DEVICE: SERRALENE, MODEL CATALOG NO 1S SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HAKKO MEDICAL CO., LTD. ATTN: SHIRO JITAGAWA 7-9 KAMIMEGURO 1-CHOME MEGURO-KU, TOKYO,	510(k) NO: K013109 PHONE NO : 81 3 4648500	DEVICE: SONOPSY SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HAMILTON THORNE RESEARCH ATTN: DIARMAID DOUGLAS-HAMPTON 100 CUMMINGS CENTER SUITE 102-C BEVERLY, MA 01915	510(k) NO: K012805 PHONE NO : 978-921-2050	DEVICE: AUTOMARQER SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HARMOS ORTHOPAEDICS, INC. ATTN: RICHARD W WOODS 1002 FREDERICK ROAD CATONSVILLE, MD 21228	510(k) NO: K014164 PHONE NO : 410-744-8367	DEVICE: GREAT TOE IMPLANT SYSTEM SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 16

HELENA LABORATORIES ATTN: PATRICIA FRANKS 1530 LINDBERGH DR. BEAUMONT, TX 77704	510(k) NO: K020467 PHONE NO : 409-842-3714	DEVICE: SPIFE LD VIS ISOENZYME KIT, MODELS 3450, 3451, AND 3452 SE DECISION MADE: 29-MAR-2002 510(k) STATEMENT
HIGHGATE ORTHOPAEDICS ATTN: KAREN E WARDEN 8202 SHERMAN ROAD CHESTERLAND, OH 44026-2141	510(k) NO: K012045 PHONE NO : 440-729-8457	DEVICE: HIGHGATE CURVED ROD SYSTEM SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HITACHI MEDICAL SYSTEMS AMERICA, ATTN: ROBERT MCCARTHY 1959 SUMMIT COMMERCE PARK TWINSBURG, OH 44087-2371	510(k) NO: K014240 PHONE NO : 330-425-1313	DEVICE: PRONTO SE DECISION MADE: 22-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOLLISTER, INC. ATTN: JOSEPH S TOKARZ 2000 HOLLISTER DR. LIBERTYVILLE, IL 60048	510(k) NO: K013612 PHONE NO : 847-680-2849	DEVICE: INCARE PELVIC FLOOR THERAPY SYSTEM SE DECISION MADE: 19-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOLLISTER, INC. ESSURE PROBE ATTN: CINDY ROBERTS 2000 HOLLISTER DR. LIBERTYVILLE, IL 60048	510(k) NO: K013653 PHONE NO : 847-918-3497	DEVICE: INCARE PRESSURE BIOFEEDBACK VAGINAL PRESSURE PROBE AND ANAL PR SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HORIZON MEDICAL PRODUCTS, INC. ATTN: PATRICIA D JONES 1 HORIZON WAY MANCHESTER, GA 31816	510(k) NO: K013871 PHONE NO : 706-846-3126	DEVICE: LIFEGUARD SAFETY INFUSION SET SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: NANCY J RIEDER 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020497 PHONE NO : 201-934-4364	DEVICE: TRIDENT ELEVATED RIM LINER SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: NANCY J RIEDER 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020572 PHONE NO : 201-934-4364	DEVICE: ACCOLADE TMZF HA 132 DEGREE SIZE 0 HIP STEM SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: WILLIAM J CYMBALUK 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020650 PHONE NO : 201-825-4900	DEVICE: MODIFICATION TO REFLEX ANTERIOR CERVICAL PLATE SYSTEM SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 17

HOWMEDICA OSTEONICS CORP. ATTN: WILLIAM J CYMBALUK 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020677 PHONE NO : 201-825-4900	DEVICE: GAMMA 3 LAG SCREW SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HUNTLEIGH HEALTHCARE, INC. ATTN: AUDRY WITKO 40 CHRISTOPHER WAY EATONTOWN, NJ 07724-3327	510(k) NO: K010744 PHONE NO : 732-578-9898	DEVICE: FLOWTRON UNIVERSAL, MODEL AC600 SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
I-FLOW CORP. P, ONE STEP KVO ATTN: SHANE NOEHRE 20202 WINDROW DR. LAKE FOREST, CA 92630	510(k) NO: K020660 PHONE NO : 949-206-2700	DEVICE: HOMEPUMP, ECLIPSE, C-SERIES, PAINBUSTER, C-BLOC, CN-Q, EASYPUM SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
I-FLOW CORP. ATTN: SHANE NOEHRE 20202 WINDROW DR. LAKE FOREST, CA 92630	510(k) NO: K020862 PHONE NO : 949-206-2700	DEVICE: I-FLOW ELASTOMERIC PUMP SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
I.Z.I. CORP. ATTN: HELEN ZINREICH 7020 TUDSBURY ROAD BALTIMORE, MD 21244	510(k) NO: K014022 PHONE NO : 410-594-9403	DEVICE: MRI LINE MARKER SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
INDUS MEDICARE LTD. ATTN: P. K REDDY 144, S.P. RD., BEGUMPET HYDERABAD ANDHRA PRADESH,	510(k) NO: K020223 PHONE NO : 914 077 60241	DEVICE: INVIGRA SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
INNERSPACE, INC. ATTN: DONALD E BOBO 2933 SOUTH PULLMAN ST., SUITE A SANTA ANA, CA 92705	510(k) NO: K013005 PHONE NO : 949-752-8672	DEVICE: ACT 11 MP VENTRICULAR CATHETER SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
INSTITUT BIOCHIMIQUE SA (IBSA) ATTN: CLARENCE E JONES 8602 MOSSFORD DRIVE HUNTINGTON BEACH, CA 92646	510(k) NO: K020041 PHONE NO : 714-963-0078	DEVICE: IALUSET HYDROCOLLOID SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
INTEGRA NEUROSCIENCES ATTN: NANCY MATHEWSON 5955 PACIFIC CENTER BLVD. SAN DIEGO, CA 92121	510(k) NO: K020558 PHONE NO : 858-455-1115	DEVICE: LICOX CC1.G2 BRAIN OXYGEN CATHETER-MICROPROBE SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 18

INTERNATIONAL TECHNIDYNE CORP. ATTN: JOHN CLAY 8 OLSEN AVENUE EDISON, NJ 08820	510(k) NO: K020798 PHONE NO : 800-272-1252	DEVICE: HEMOCHRON JR. SIGNATURE + SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
INTERPORE CROSS INIL. ATTN: PROISE REY-FESSLER 181 TECHNOLOGY DR. IRVINE, CA 92618-2402	510(k) NO: K012406 PHONE NO : 949-453-3200	DEVICE: ACCESS SEQUESTRATION SYSTEM SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
IVOCLAR VIVADENT, INC. ATTN: ANDERJEET GULATI 175 PINEVIEW DR. AMHERST, NY 14228	510(k) NO: K020183 PHONE NO : 716-691-0010	DEVICE: PISCES PLUS (DW286 C) SE DECISION MADE: 13-MAR-2002 510(k) STATEMENT
IVOCLAR VIVADENT, INC. ATTN: ANDERJEET GULATI 175 PINEVIEW DR. AMHERST, NY 14228	510(k) NO: K020898 PHONE NO : 716-691-0010	DEVICE: D.SIGN 15 (DW286 B) SE DECISION MADE: 29-MAR-2002 510(k) STATEMENT
J. MORITA USA, INC. ATTN: KEITH A BARRITT 601 13TH STREET, N.W. SUITE 500 NORTH WASHINGTON, DC 20005	510(k) NO: K012849 PHONE NO : 202-783-5070	DEVICE: GLASS POST SE DECISION MADE: 27-MAR-2002 510(k) STATEMENT
J. MORITA USA, INC. ATTN: KEITH A BARRITT 601 13TH STREET, N.W. WASHINGTON, DC 20005	510(k) NO: K020157 PHONE NO : 202-626-6433	DEVICE: TEMPORARY CROWN AND BRIDGE MATERIAL SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
J. MORITA USA, INC. ATTN: KEITH A BARRITT 601 13TH STREET, N.W. WASHINGTON, DC 20005	510(k) NO: K020158 PHONE NO : 202-783-5070	DEVICE: NON-EUGENOL TEMPORARY CEMENT SE DECISION MADE: 07-MAR-2002 510(k) STATEMENT
JAMES D RUSIN MD, MBA ATTN: JAMES D RUSIN 3512 RUM RIVER DRIVE ANOKA, MN 55303-1109	510(k) NO: K014300 PHONE NO : 612-242-8037	DEVICE: SAFETOUCH SE DECISION MADE: 01-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
JAWON MEDICAL CO., LTD. ATTN: WON-HEE PARK JECONG-JU B/D 7F,1451-38, SEOCHO-DONG SEOUL,	510(k) NO: K013876 PHONE NO : 011 82 25874056	DEVICE: INFRARED EAR THERMOMETER, MODEL DX-707 SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 19

JOSTRA AG ATTN: KATHLEEN JOHNSON 478 MEDIA ROAD OXFORD, PA 19363	510(k) NO: K014303 PHONE NO : 610-932-7738	DEVICE: JOSTRA RETROGRADE CARDIOPLEGIA CANNULAE SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
K-JUMP HEALTH CO., LTD. ATTN: JONATHAN S KAHAN 555 THIRTEEN STREET, N.W. WASHINGTON, DC 20004-1109	510(k) NO: K014204 PHONE NO : 202-637-5794	DEVICE: ARM BLOOD PRESSURE MONITOR, MODELS KP-6821, KP-6822 SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
KERR CORPORATION (DANBURY) ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92867	510(k) NO: K020091 PHONE NO : 714-516-7484	DEVICE: OPTILUX 501 SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
KERR DENTAL MATERIALS CENTER ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92867	510(k) NO: K020178 PHONE NO : 714-516-7484	DEVICE: BELLEGLASS HP MODELING GEL SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
KLS-MARTIN L.P. ATTN: ARTHUR WARD 962 ALLEGRO LANE APOLLO BEACH, FL 33572	510(k) NO: K011590 PHONE NO : 813-645-2855	DEVICE: RESORB-X RESORBABLE PLATING SYSTEM SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
KONICA CORP. ATTN: SHINICHI YAMANAKA 319 AKENO, OBATA-CHO WATARAI-GUN MIE-KEN,	510(k) NO: K013054 PHONE NO : 011 815 96373609	DEVICE: KONICA DIRECT DIGITIZER REGIUS MODEL 350 SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
LATEX MANUFACTURING SDN.BHD. REE RUBBER LATEX EXAMINATION GLOVE ATTN: YOLANDA SMITH P.O. BOX 4341 CROFTON, MD 21114	510(k) NO: K014087 PHONE NO : 410-451-0639	DEVICE: LATEXX MANUFACTURING NON-CHLORINATED, POLYMER COATED, POWDER-F SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
LENS DYNAMICS, INC. ATTN: AL VASKE 8600 WEST 14TH AVE., #2 LAKEWOOD, CO 80215	510(k) NO: K020006 PHONE NO : 303-237-6927	DEVICE: DYNA INTRA-LIMBAL LENS SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
LEV-EL, LTD. ATTN: EINAT SHAMMAI MIZPE AVIV INDUSTRIAL PARK 13 M.P. MISGAV,	510(k) NO: K012825 PHONE NO : 972 499 47880	DEVICE: HEARTTRENDS SE DECISION MADE: 19-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 20

MAINE STANDARDS CO. ATTN: CHRISTINE BEACH 765 ROOSEVELT TRAIL SUITE 9A WINDHAM, ME 04062-5365	510(k) NO: K020450 PHONE NO : 207-892-1300	DEVICE: VALIDATE CHEM 8 CALIBRATION VERIFICATION TEST SET; MODEL 108 SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MARKETING SALES CONCEPTS, INC. ATTN: ERIC J ARTHUR 200 RENAISSANCE COMPANY SUITE 111 ATLANTA, GA 30308	(MS510(k) NO: K011363 PHONE NO : 404-815-4596	DEVICE: JOE LUBE CONDOM SE DECISION MADE: 25-MAR-2002 510(k) STATEMENT
MARKETING SALES CONCEPTS, INC. ATTN: ERIC J ARTHUR 200 RENAISSANCE COMPANY SUITE 111 ATLANTA, GA 30308	(MS510(k) NO: K011378 PHONE NO : 404-815-4596	DEVICE: JOE LUB "HELMET" CONDOM SE DECISION MADE: 25-MAR-2002 510(k) STATEMENT
MEDELA, INC. ATTN: WERNER FREI LAETTICHSTRASSE 4B BARR, ZUG,	510(k) NO: K020518 PHONE NO : 41 41 7695228	DEVICE: MEDELA SYMPHONY BREASTPUMP, MODEL 024 SE DECISION MADE: 07-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL COMPRESSION SYSTEMS (DEN) ATTN: SHOSHANA FRIEDMAN 117 AHUZAH ST. RA'ANANNA,	510(k) NO: K012994 PHONE NO : 972 9 7718130	DEVICE: WIZAIR DVT SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC MIDAS REX IGH SPEED SYSTEM OR LEGEND SYSTEM ATTN: GREG CANNEDY 4620 NORTH BEACH STREET FORT WORTH, TX 76137	510(k) NO: K020069 PHONE NO : 817-788-6503	DEVICE: MEDTRONIC MIDA REX LEGEND SYSTEM, MIDAS REX LEGEND PNEUMATIC H SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC SOFAMOR DANEK USA, INC. ATTN: RICHARD W TREHARNE 1800 PYRAMID PLACE MEMPHIS, TN 38132	510(k) NO: K012506 PHONE NO : 901-396-3133	DEVICE: MASTERGRAFT RESORBABLE CERAMIC GRANULES SE DECISION MADE: 07-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MENNEN MEDICAL LTD. ATTN: ASHER KASSEL KIRYAT WEIZMANN SCIENCE PARK P.O. BOX 102 REHOVOT,	510(k) NO: K020632 PHONE NO : 972 8 9383030	DEVICE: ENGUARD REMOTE PATIENT MONITOR SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MERIDIAN MEDICAL TECHNOLOGIES, INC. ATTN: JAMIL F LAHAM 10240 OLD COLUMBIA RD. COLUMBIA, MD 21046	510(k) NO: K012414 PHONE NO : 410-309-6830	DEVICE: PRIME ECG SYSTEM SE DECISION MADE: 06-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 21

MESURE TECHNOLOGY , ST8532F, ST8542C, AND ST8542F ATTN: PHIL ZULUETA 34138 COURINEY TERRACE ACTON, CA 93510	510(k) NO: K013779 PHONE NO : 661-269-1006	DEVICE: THERMOMETER MODELS ST8132C, ST8132F, ST8142C, ST8142F, ST8532C SE DECISION MADE: 29-MAR-2002 510(k) STATEMENT
MICROAIRE SURGICAL INSTRUMENTS, ATTN: CARL ANGLES 1641 EDLICH DR. CHARLOTTESVILLE, VA 22911	IN510(k) NO: K014060 PHONE NO : 434-975-8000	DEVICE: MICROAIRE 1000E SYSTEM SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MICROLIFE CORP. ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD. SUITE 200 GREAT NECK, NY 11021	510(k) NO: K020725 PHONE NO : 516-482-9001	DEVICE: MICROLIFE DIGITAL INFRARED EAR THERMOMETER, MODEL IR1DE1 SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MILLENNIUM DENTAL TECHNOLOGIES, ATTN: DAVID M HARRIS 4256 HEYER AVENUE CASTRO VALLEY, CA 94546	IN510(k) NO: K014272 PHONE NO : 510-583-7574	DEVICE: PERIOLASE ND:YAG DENTAL LASER SYSTEM SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MILLENNIUM MEDICAL TECHNOLOGIES, ATTN: DAVID W SCHLERF 200 GREGORY LANE SUITE C-100 PLEASANT HILL, CA 94523-3389	I510(k) NO: K012294 PHONE NO : 925-356-2640	DEVICE: WRISTORE FIXATOR SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MITEK PRODUCTS ATTN: CHRISTINE KUNTZ-NASSIF 249 VANDERBILT AVE. NORWOOD, MA 02062	510(k) NO: K013572 PHONE NO : 781-251-2794	DEVICE: MITEK BIOCRYL INTERFERENCE SCREWS SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
MOVINGPEOPLE.NET ATTN: PEGGY SPILIADIS 500 NORTINCH DRIVE TORONTO, ONTARIO,	510(k) NO: K020737 PHONE NO : 416 739 8333	DEVICE: CAT ACTIVE WHEELCHAIR SE DECISION MADE: 21-MAR-2002 510(k) STATEMENT
MRI DEVICES CORP. ATTN: TOM SCHUBERT 1515 PARAMOUNT DR. SUITE A WAUKESHA, WI 53186	510(k) NO: K020606 PHONE NO : 262-524-1402	DEVICE: NVA-63-8 NEUROVASCULAR ARRAY COIL SE DECISION MADE: 13-MAR-2002 510(k) STATEMENT
MTP MEDICAL TECHNICAL PROMOTION ATTN: JAMES A LEE 600 CORPORATE POINTE CULVER CITY, CA 90230	GM510(k) NO: K020599 PHONE NO : 310-410-2769	DEVICE: MTP CLEARVISION DISPOSABLE TUBING SET SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 22

NATS CORP. ATTN: RICHARD C LANZILLOTTO 30 NORTHPORT ROAD SOUND BEACH, NY 11789-1734	510(k) NO: K020060 PHONE NO : 631-744-0059	DEVICE: ASTOFLO SE DECISION MADE: 05-MAR-2002 510(k) STATEMENT
NELCOR PURITAN BENNETT, INC. MAX SENSORS AND CABLES (AKA "ACCESSORIES") ATTN: RONALD J EHMSEN 4280 HACIENDA DR. PLEASANTON, CA 94588-2719	510(k) NO: K012891 PHONE NO : 925-463-4371	DEVICE: OXIMAX PULSE OXIMETRY SYSTEM WITH N-595 PULSE OXIMETER AND OXI SE DECISION MADE: 07-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NEOTHERMIA CORP. 2, 777-006, 777-301, 777-302 ATTN: SHERRIE COVAL-GOLDSMITH ONE APPLE HILL SUITE 316 NATICK, MA 01760	510(k) NO: K020031 PHONE NO : 508-655-7820	DEVICE: EN-BLOC BIOPSY SYSTEM, MODELS 777-110, 777-120, 770-001, 77700 SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NORTHWEST MEDICAL PHYSICS EQUIPMENT ATTN: LEE MYERS 21031 67TH AVE. WEST LYNNWOOD, WA 98036	510(k) NO: K012575 PHONE NO : 425-672-2841	DEVICE: PREFERENCE IMRT TREATMENT PLANNING MODULE SE DECISION MADE: 12-MAR-2002 510(k) STATEMENT
NOTAL VISION, INC. ATTN: RICHARD E LIPPMAN 12300 TWINBROOK PKWAY; STE 625 ROCKVILLE, MD 20852	510(k) NO: K014044 PHONE NO : 301-770-9590	DEVICE: MASCLAR COMPUTERIZED PSYCHOPHYSICAL TEST (MCPT) SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NTERO SURGICAL, INC. ATTN: BONNI BOMMANNAN 1137D SAN ANTONIO RD. PALO ALTO, CA 94303-4310	510(k) NO: K014251 PHONE NO : 650-428-1000	DEVICE: NTERO HOTROD SYSTEM SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NUCLEAR CARDIOLOGY SYSTEMS, INC. ATTN: CHARLES H ROSE 5660 AIRPORT BLVD., SUITE 101 BOULDER, CO 80301	510(k) NO: K013353 PHONE NO : 303-541-0044	DEVICE: NEUROSPPECTQUAD GAMMA CAMERA SE DECISION MADE: 04-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NUCLETRON CORP. ATTN: LISA DIMMICK 7080 COLUMBIA GATEWAY DR. COLUMBIA, MD 21046-2133	510(k) NO: K020015 PHONE NO : 410-312-4100	DEVICE: IMPLANT GUIDANCE SYSTEM APPLICATOR SET SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NUVASIVE, INC. ATTN: LAETTITA BERNARD 10065 OLD GROVE RD. SAN DIEGO, CA 92131	510(k) NO: K020411 PHONE NO : 858-527-1918	DEVICE: NUVASIVE TRIAD FACET SCREW SYSTEM SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 23

NKSTAGE MEDICAL, INC. SERVOIR ATTN: KAREN ST. ONGE 439 SOUTH UNION STREET SUITE 501 S. LAWRENCE, MA 01843	510(k) NO: K011269 PHONE NO : 978-687-4700	DEVICE: LIFEMATE MLA MULTI-LINE ADAPTOR; LIFEMATE SFR STERILE FLUID RE SE DECISION MADE: 05-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
OCULAR INSTRUMENTS, INC. ATTN: RAYMOND GRAHAM 2255 116TH AVE., N.E. BELLEVUE, WA 98004-3039	510(k) NO: K014170 PHONE NO : 425-455-5200	DEVICE: STAURENGHI WIDE FIELD SCANNING LASER LENS SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
ONUX MEDICAL, INC. ATTN: RUTHANN DEPIETRO 5 MERRILL DR. HAMPTON, NH 03842	510(k) NO: K014286 PHONE NO : 603-929-6200	DEVICE: SALUTE, MODEL 3022 SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
OPTONOL, LTD TS VERSIONS ATTN: RICHARD E LIPPMAN 12300 TWINEROCK PKWY, STE 625 ROCKVILLE, MD 20852	510(k) NO: K012852 PHONE NO : 301-770-9590	DEVICE: EX-PRESS MINATURE GLAUCOMA IMPLANT, MODELS R-20, R-30, R-50, S SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ORGANOGENESIS, INC. ATTN: PATRIC BILBO 150 DAN RD. CANTON, MA 02021	510(k) NO: K020049 PHONE NO : 781-401-1155	DEVICE: FORTAFLEX SURGICAL MESH SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ORTHOPEDIC DESIGNS, INC. ATTN: JOHN SODEIKA 6965 1ST AVE., NORTH ST. PETERSBURG, FL 33710-8303	510(k) NO: K014189 PHONE NO : 727-343-0338	DEVICE: CDI TALON INTRAMEDULLARY HIP NAIL SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
OSCOR INC. B, RB, JB, RJB ATTN: MILA DOSKOCIL 3816 DE SOTO BLVD. PALM HARBOR, FL 34683	510(k) NO: K020669 PHONE NO : 727-937-2511	DEVICE: PERMANENT PACING LEAD, MODELS PETITE, PETITE R, J, RJ, PETITE SE DECISION MADE: 28-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PARADIGM TREX, LLC ATTN: NIKOLAI TANKOVICH 10455 PACIFIC CENTER CT. SAN DIEGO, CA 92121-4339	510(k) NO: K014253 PHONE NO : 858-646-5721	DEVICE: DERMACHILLER 4 SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PARKELL, INC. ATTN: NELSON J GENDUSA 155 SCHMITT BLVD. P.O. BOX 376 FARMINGDALE, NY 11735	510(k) NO: K020239 PHONE NO : 631-249-1134	DEVICE: TOUCH&BOND-PLUS SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 24

PASCO LABORATORIES, INC. ATTN: LINDA K DILLON 12750 WEST 42ND AVE. WHEAT RIDGE, CO 80033	510(k) NO: K020331 PHONE NO : 800-321-9813	DEVICE: PASCO MIC AND MIC/ID PANELS SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PELVICFLEX, INC. ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD. SUITE 200 GREAT NECK, NY 11021	510(k) NO: K011688 PHONE NO : 203-431-1511	DEVICE: PELVICFLEXER EXERCISE DEVICE SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PERLEI MEDICAL, INC. ATTN: ART WARD 962 ALLEGRO LANE APOLLO BEACH, FL 33572	510(k) NO: K014268 PHONE NO : 813-645-2855	DEVICE: NORAPAD PLAIN; NORAPAD TA SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS ATTN: LYNN HARMER 22100 BOTHELL EVERETT HWY BOTHELL, WA 98021-8431	510(k) NO: K020055 PHONE NO : 425-487-7312	DEVICE: PHILIPS INTEGRIS ALLURA 9 WITH FD OPTION SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS T COMPACT MONITOR, RELEASE A.02, MODEL M1275B ATTN: DAVE OSBORN 3000 MINUTEMAN RD. ANDOVER, MA 01810	510(k) NO: K020531 PHONE NO : 978-659-3178	DEVICE: PHILIPS MULTI-PARAMETER MODULE, MODEL M3001A; PHILIPS COMPONENT SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PISHARODI SURGICALS, INC. ATTN: MADHAVEN PISHARODI 942 WILDROSE LANE BROWNSVILLE, TX 78520	510(k) NO: K014302 PHONE NO : 956-541-6725	DEVICE: UNIVERSAL MULTITAXIS (UNIMAX) PEDICLE SCREW SYSTEM SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PLAYTEX PRODUCTS, INC. ATTN: MARK ROSENGARTEN 75 COMMERCE DR. ALLENDALE, NJ 07401-1600	510(k) NO: K020200 PHONE NO : 201-785-8040	DEVICE: PLAYTEX DEODORANT TAMPONS, MODEL 34802 SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PLAYTEX PRODUCTS, INC. ATTN: MARK ROSENGARTEN 75 COMMERCE DR. ALLENDALE, NJ 07401-1600	510(k) NO: K020201 PHONE NO : 201-785-8040	DEVICE: PLAYTEX DEODORANT TAMPONS, MODEL 34902 SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PLAYTEX PRODUCTS, INC. ATTN: MARK ROSENGARTEN 75 COMMERCE DR. ALLENDALE, NJ 07401-1600	510(k) NO: K020202 PHONE NO : 201-785-8040	DEVICE: PLAYTEX DEODORANT TAMPONS, MODEL 34702 SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 25

FOREX SURGICAL, INC. ATTN: HOWARD MERCER 15 DART RD. NEWNAN, GA 30265	510(k) NO: K012350 PHONE NO : 678-479-1610	DEVICE: MEDPOR PLUS SURGICAL IMPLANT BIOMATERIAL SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PRECISION VASCULAR SYSTEMS, INC. ATTN: RICK GAYKOWSKI 2405 WEST ORION CIR. WEST VALLEY CITY, UT 84119	510(k) NO: K020733 PHONE NO : 801-974-1736	DEVICE: PVS 1500 SDS SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PROCERA SANDVIK AB ATTN: AGNETA ODEN LERKROGSAVAGEN 19 VASTBERGA STOCKHOLM,	510(k) NO: K020269 PHONE NO : 468 726 6619	DEVICE: PROCERA ALLCERAM BRIDGE MATERIAL SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PROMEDON ATTN: DEBBIE IAMPIETRO 7 MAIN STREET ESSEX JUNCTION, VT 05452	510(k) NO: K020007 PHONE NO : 508-435-9893	DEVICE: SAFYRE SLING SYSTEM SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PULPDENT CORP. ATTN: KENNETH J BERK 80 OAKLAND STREET WATERTOWN, MA 02472	510(k) NO: K014133 PHONE NO : 617-926-6666	DEVICE: PULPDENT NO-MIX ORTHODONTIC BRACKET ADHESIVE SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
PULPDENT CORP. ATTN: KENNETH J BERK 80 OAKLAND STREET WATERTOWN, MA 02472	510(k) NO: K014138 PHONE NO : 617-926-6666	DEVICE: PULPDENT TRIPLE-CURE REINFORCED GLASS IONOMER ORTHODONTIC CEMENT SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
QUANTIMETRIX CORP. ATTN: GERHARD NEYER 2005 MANHATTAN BEACH BLVD. REDONDO BEACH, CA 90278-1205	510(k) NO: K013662 PHONE NO : 310-536-0006	DEVICE: MODIFICATION TO LIPOPRINT SYSTEM, LDL SUBFRACTIONS SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
REGULATORY INSIGHT, INC. 600-663, EN 600-665 AND EN 600-670 MECHANICAL WHEELCHAIRS ATTN: KEVIN WALLS 13 RED FOX LN. LITTLETON, CO 80127	510(k) NO: K020094 PHONE NO : 720-962-5412	DEVICE: EN 600-658, EN 600-666, EN 600-664, EN 600-690, EN 600-651, EN SE DECISION MADE: 08-MAR-2002 510(k) STATEMENT
REGULATORY INSIGHT, INC. 801 MECHANICAL WHEELCHAIRS ATTN: KEVIN WALLS 13 RED FOX LN. LITTLETON, CO 80127	510(k) NO: K020100 PHONE NO : 720-962-5412	DEVICE: SL 803, SL 804, SL 807, SL 809, SL 506, SL 501, SL 805 AND SL SE DECISION MADE: 08-MAR-2002 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 26

RESPIRONICS, INC. ATTN: ZITA A YURKO 1001 MURRY RIDGE LANE MURRYSVILLE, PA 15668	510(k) NO: K020777 PHONE NO : 724-387-4120	DEVICE: BIPAP SYNCHRONY VENTILATORY SUPPORT SYSTEM WITH BI-FLEX SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ROCHE DIAGNOSTICS CORP. ATTN: SCOTT THIEL 9115 HAGUE RD. INDIANAPOLIS, IN 46250	510(k) NO: K014139 PHONE NO : 800-428-5074	DEVICE: DIABETES ASSISTANT SOFTWARE SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ROCHE DIAGNOSTICS CORP. ATTN: SHERRI L COENEN 9115 HAGUE RD. INDIANAPOLIS, IN 46250	510(k) NO: K020369 PHONE NO : 317-521-3831	DEVICE: ELECSYS ANTI-TG CALCHECK SE DECISION MADE: 06-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SA SCIENTIFIC, INC. ATTN: RICARDO R MARTINEZ 4919 GOLDEN QUAIL SAN ANTONIO, TX 78240	510(k) NO: K020438 PHONE NO : 210-699-8800	DEVICE: SAS VALUE HOG SE DECISION MADE: 08-MAR-2002 510(k) STATEMENT
SANARUS MEDICAL, INC. ATTN: VINCENT CUTARELLI 5880 WEST LAS POSITAS,SUITE 52 PLEASANTON, CA 94588	510(k) NO: K020605 PHONE NO : 949-768-1184	DEVICE: SANARUS VISICA TREATMENT SYSTEM SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SCIENCE INCORPORATED RAL KIT ATTN: LYNN WEIST 12150 NICOLLET AVENUE SOUTH BURNSVILLE, MN 55337-1647	510(k) NO: K020881 PHONE NO : 952-835-1333	DEVICE: MODIFICATION TO PERSONAL INFUSOR LOCAL PAIN MANAGEMENT PROCEDU SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SEQUAL TECHNOLOGIES, INC. ATTN: PAM JACKSON 11436 SORRENTO VALLEY RD. SAN DIEGO, CA 92121-1393	510(k) NO: K013931 PHONE NO : 858-202-3100	DEVICE: OMNI OXYGEN SYSTEM, MODEL 1000 SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SIAM SEMPERMED CORP. LTD. NATION GLOVES WITH PROTEIN CONTENT LABELING CLAIM (50 MICS ATTN: KATIE LEVINSON 30798 US HWY 19 NORTH PALM HARBOR, FL 34684	510(k) NO: K013267 PHONE NO : 727-787-7250	DEVICE: POWDER FREE (POLYMER COATED) NON CHLORINATED WHITE LATEX EXAMI SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SOLUTIONS USA, INC ATTN: JAMES YIEH 186 WOOD AVENUE SOUTH ISELIN, NJ 08830	510(k) NO: K020573 PHONE NO : 732-321-4625	DEVICE: MODIFICATION TO MAGNETOM RHAPSODY SYSTEM SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 27

SIMAD S.R.L. ATTN: JEFFREY S KEES 70 WEILL WAY WILMINGTON, OH 45177	510(k) NO: K013426 PHONE NO : 937-382-1451	DEVICE: MOONRAY MOBILE C-ARM SE DECISION MADE: 26-MAR-2002 510(k) STATEMENT
SMITH & NEPHEW, INC. ONENTS IN THE GENESIS KNEE SYSTEM, THE GENESIS II KNEE SYS ATTN: DAVID HENLEY 1450 E. BROOKS ROAD MEMPHIS, TN 38116	510(k) NO: K012778 PHONE NO : 901-399-6487	DEVICE: VAPORIZED HYDROGEN PEROXIDE (VHP) STERILIZATION OF UHMWPE COMP SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW, INC. ONENTS IN THE REFLECTION ACTABULAR SYSTEM (ACETABULAR LINE ATTN: DAVID HENLEY 1450 E. BROOKS ROAD MEMPHIS, TN 38116	510(k) NO: K012787 PHONE NO : 901-399-6487	DEVICE: VAPORIZED HYDROGEN PEROXIDE (VHP) STERILIZATION OF UHMWPE COMP SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW, INC. ONENTS IN THE COFIELD TOTAL SHOULDER SYSTEM, THE NEER II ATTN: DAVID HENLEY 1450 E. BROOKS ROAD MEMPHIS, TN 38116	510(k) NO: K012788 PHONE NO : 901-399-6487	DEVICE: VAPORIZED HYDROGEN PEROXIDE (VHP) STERILIZATION OF UHMWPE COMP SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW, INC. ATTN: WILLIAM MCCALLUM 160 DASCOMB RD. ANDOVER, MA 01810	510(k) NO: K020159 PHONE NO : 508-261-3658	DEVICE: SMITH & NEPHEW TWINFIX TI QUICK T SE DECISION MADE: 26-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW, INC. ATTN: WILLIAM MCCALLUM 130 FORBES BLVD. MANSFIELD, MA 02048	510(k) NO: K020480 PHONE NO : 508-261-3770	DEVICE: REM SE DECISION MADE: 12-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SOPHYSA SA ATTN: JACQUELINE E MASSE 70 WALNUT STREET WELLESLEY, MA 02481	510(k) NO: K013488 PHONE NO : 781-239-8108	DEVICE: SOPHY PRESSURE ADJUSTABLE VALVE SYSTEM MODEL SMB SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SOPRO ATTN: PIERRE MONTILLOT PLACE ST. CHRISTOPHE LES ACCATES-LA VALENTINE MARSEILLE,	510(k) NO: K020270 PHONE NO : 33 4 91270727	DEVICE: SOPRO 367D 30CD FULL DIGITAL ENDOSCOPY CAMERA SE DECISION MADE: 14-MAR-2002 510(k) STATEMENT
SPINAL CONCEPTS, INC. ATTN: DAVID M HOOPER 12012 TECHNOLOGY BLVD., #100 AUSTIN, TX 78727	510(k) NO: K020611 PHONE NO : 512-918-2700	DEVICE: UNIVERSAL BONE PLATE III SYSTEM (UBP III) SE DECISION MADE: 27-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 28

SSL AMERICAS, INC. ATTN: JOYCE NING 3585 ENGINEERING DR.; STE 200 P.O. BOX 926090 NORCROSS, GA 30092-9214	510(k) NO: K020659 PHONE NO : 770-582-2152	DEVICE: DUREX LATEX CONDOM WITH MALE GENITAL DESENSITIZER LUBRICANT SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
STERITEC PRODUCTS, INC. ATTN: LINDA NELSON 599 TOPEKA WAY, SUITE 700 CASTLE ROCK, CO 80104	510(k) NO: K012732 PHONE NO : 303-660-4201	DEVICE: INTEGRAPH FLASH, MODEL CI 110 SE DECISION MADE: 04-MAR-2002 510(k) STATEMENT
STERNGOLD ATTN: MARIA RAO 23 FRANK MOSSEBERG DR. ATTLEBORO, MA 02703-0967	510(k) NO: K020391 PHONE NO : 508-226-5660	DEVICE: STERN MICRO ERA ATTACHMENT SYSTEM SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
STRYKER ENDOSCOPY ATTN: ALISA MILLER 2590 WALSH AVE. SANTA CLARA, CA 95051	510(k) NO: K020097 PHONE NO : 408-567-9100	DEVICE: STRYKER INTERFERENCE SCREW CROSS PIN SYSTEM SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
STRYKER INSTRUMENTS ATTN: ROBIN L ROWE 4100 EAST MILHAM AVE. KALAMAZOO, MI 49001-6197	510(k) NO: K014263 PHONE NO : 616-323-7700	DEVICE: NEWGEN/UNIVERSAL MANDIBULAR SYSTEM SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SULZER DENTAL, INC. ATTN: SEAN HARIRI 1900 ASTON AVE. CARLSBAD, CA 92008-7308	510(k) NO: K014175 PHONE NO : 760-929-4300	DEVICE: SULZER DENTAL CERAMIC SYSTEM-HEXLOCK SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SULZER DENTAL, INC. ATTN: SEAN HARIRI 1900 ASTON AVE. CARLSBAD, CA 92008-7308	510(k) NO: K014214 PHONE NO : 760-929-4300	DEVICE: SULZER DENTAL CERAMIC SYSTEM-SPLINE SE DECISION MADE: 19-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SUN BIOMEDICAL LABORATORIES, INC. ATTN: MING SUN 604 VPR CENTER 1001 LOWER LANDING RD. BLACKWOOD, NJ 08012	510(k) NO: K020136 PHONE NO : 856-401-1080	DEVICE: VISUALINE BARBITURATES DIPSTRIP TEST SE DECISION MADE: 20-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SUPERMAX GLOVE MANUFACTURING SDN CLAIM (50 MICROGRAM OR LESS) ATTN: STANLEY THAI LOT 42, PUTRA INDUSTRIAL PARK BUKIT RAHMAN PUTRA SUNGAI BULOH, SELANGOR,	510(k) NO: K014230 PHONE NO : 603 615 72328	DEVICE: STERILE POWDER FREE LATEX SURGEON GLOVES WITH PROTEIN LABELING SE DECISION MADE: 13-MAR-2002 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 29

SUPERMAX SDN BHD H ALOE VERA ATTN: PRISCILLA WEE LOT 42, PUTRA INDUSTRIAL PARK BUKIT RAHMAN PUTRA SUNGAI PELONG, SELANGOR,	510(k) NO: K013774 PHONE NO : 603 615 72328	DEVICE: CHLORINATED POWDER FREE NITRILE MEDICAL EXAMINATION GLOVES WITH SE DECISION MADE: 05-MAR-2002 510(k) STATEMENT
SURETONE INTERNATIONAL ATTN: MARYNA BURKE 2 PRESEDENT BRAND STREET PANORAMA CAPE TOWN, CAPE,	510(k) NO: K011588 PHONE NO : 272 193 98251	DEVICE: SURETONE SE DECISION MADE: 28-MAR-2002 510(k) STATEMENT
SURGILIGHT, INC. ATTN: TIMOTHY SHEA 12001 SCIENCE DRIVE SUITE 140 ORLANDO, FL 32826	510(k) NO: K020973 PHONE NO : 407-482-4555	DEVICE: EX-308 EXCIMER LASER FOR PHOTOTHERAPY TREATMENT OF VITILIGO SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SURX, INC. SYSTEM AND ACCESSORIES (SURX TV SYSTEM) ATTN: ALAN CURTIS 2675 COLLIER CANYON RD. LIVERMORE, CA 94550	510(k) NO: K020126 PHONE NO : 925-398-4521	DEVICE: MODIFICATION TO SURX RADIOFREQUENCY ELECTROSURGICAL GENERATOR SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SYBERON DENTAL SPECIALTIES, INC. ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92667	510(k) NO: K020267 PHONE NO : 714-516-7484	DEVICE: OPTILUX CURING LIGHTS SE DECISION MADE: 29-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
SYNTHES (USA) ATTN: MATTHEW M HULL 1690 RUSSELL RD. PAOLI, PA 19301	510(k) NO: K014197 PHONE NO : 610-647-9700	DEVICE: SYNTHES HIGH TIBIAL OSTECTOMY PLATE SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
TAIWAN ARMADA ENTERPRISE CO., LTD. ATTN: KE-MIN JEN NO. 58, FU-CHIUN ST. HSIN-CHU CITY,	510(k) NO: K020188 PHONE NO : 886 3 5208829	DEVICE: BIOTECH MANUAL WHEELCHAIR, A1000 SUPER SPORT WHEELCHAIR SE DECISION MADE: 08-MAR-2002 510(k) STATEMENT
TAIWAN ARMADA ENTERPRISE CO., LTD. ATTN: KE-MIN JEN NO. 58, FU-CHIUN ST. HSIN-CHU CITY,	510(k) NO: K020472 PHONE NO : 886 3 5208829	DEVICE: BIOTECH MANUAL WHEELCHAIR B900 SUPER LIGHT WHEELCHAIR SE DECISION MADE: 08-MAR-2002 510(k) STATEMENT
TECO DIAGNOSTICS ATTN: OLIVIA CHEN 1268 . LAKEVIEW AVE. ANAHEIM, CA 92807	510(k) NO: K020175 PHONE NO : 714-693-7788	DEVICE: URS-IG (GLUCOSE TEST) SE DECISION MADE: 21-MAR-2002 510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 30

TELEMED SYSTEMS, INC.
ATTN: MICHAEL CARROLL
8 KANE INDUSTRIAL DRIVE
HUDSON, MA 01749

510(k) NO: K013737
PHONE NO : 978-567-9033

DEVICE: MODIFICATION TO: 3-LUMEN DURALON OCCLUSION BALLOON
SE DECISION MADE: 01-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TENACORE HOLDINGS, INC.
ATTN: BRAND CASO
23266 VIA RONDA
MISSION VIEJO,, CA 92691

510(k) NO: K012041
PHONE NO : 949-362-1350

DEVICE: THE HAMMER MODEL H100
SE DECISION MADE: 28-MAR-2002
510(k) STATEMENT

TISSUELINK MEDICAL, INC.
ATTN: VICKI ANASTASI
ONE WASHINGTON CENTER
SUITE #400
DOVER, NH 03820

510(k) NO: K014260
PHONE NO : 603-742-1515

DEVICE: TISSUELINK SOLID CYLINDER MONOPOLAR DEVICE
SE DECISION MADE: 27-MAR-2002

510(k) SUMMARY AVAILABLE FROM FDA

TITAN IMPLANTS
ATTN: LYNETTE L HOWARD
203 MAIN STREET, PMB 166
FLEMINGTON, NJ 08822

510(k) NO: K001638
PHONE NO : 908-788-4580

DEVICE: O-RING PROSTHETIC ATTACHMENT
SE DECISION MADE: 04-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TOP QUALITY MFG., INC.
NT LABELING CLAIM (200 MICROGRAMS
OR LESS)
ATTN: MARC SINKOW
6800 LINDBERGH AVE.
PHILADELPHIA, PA 19142

510(k) NO: K013821
PHONE NO : 215-365-6100

DEVICE: SILK TOUCH POWDERED LATEX EXAMINATION GLOVE WITH PROTEIN CONTE
SE DECISION MADE: 05-MAR-2002
510(k) STATEMENT

TRANSONIC SYSTEMS, INC.
W METER, MODELS HQ100 AND HQ101
ATTN: MARK S ALSEERGE
34 DUTCH MILL RD.
ITHACA, NY 14850-9787

510(k) NO: K010253
PHONE NO : 607-257-5300

DEVICE: ANGIO FLOW THERMODILUTION CATHETER, MODEL AF-CATH-01; ANGIOFLC
SE DECISION MADE: 19-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TRANSWORLD MOBILITY DISTRIBUTION,
ATTN: JUAN C RIVERA
6140 MID METRO DRIVE
SUITE #6
FORT MYERS, FL 33912

510(k) NO: K020001
PHONE NO : 941-275-6767

DEVICE: PF-3, BATTERY OPERATED, FOUR WHEEL, POWER SCOOTER, MODEL PF-3
SE DECISION MADE: 21-MAR-2002

510(k) SUMMARY AVAILABLE FROM FDA

TRANSWORLD MOBILITY DISTRIBUTION,
EL P-33
ATTN: JUAN C RIVERA
6140 MID METRO DRIVE
SUITE #6
FORT MYERS, FL 33912

510(k) NO: K020002
PHONE NO : 941-275-6767

DEVICE: MODEL P-33, BATTERY OPERATED, THREE WHEEL, POWER SCOOTER , MOD
SE DECISION MADE: 21-MAR-2002

510(k) STATEMENT

TREK DIAGNOSTIC SYSTEMS, INC. ATTN: CYNTHIA C KNAPP 29299 CLEMENS RD. SUITE 1-K WESTLAKE, OH 44145	510(k) NO: K014259 PHONE NO : 800-216-9036	DEVICE: SENSITIVE HEAMOPHILUS/STREPTOCOCCUS PNEUMONIAE (HP) MIC PLATE SE DECISION MADE: 26-MAR-2002 510(k) STATEMENT
TRIAGE MEDICAL INC E , MODEL BMCD-35-3040, MBCD-35-4050 ATTN: BRAD CULBERT 13700 ALTON PARKWAY SUITE 167 IRVINE, CA 92618	510(k) NO: K014243 PHONE NO : 949-472-0006	DEVICE: BONE-LOK BIOABSORBABLE COMPRESSION ANCHOR WITH TITANIUM FLXTUR SE DECISION MADE: 26-MAR-2002 510(k) STATEMENT
TRIAGE MEDICAL INC ATTN: BRAD CULBERT 13700 ALTON PARKWAY SUITE 167 IRVINE, CA 92618	510(k) NO: K014304 PHONE NO : 949-472-0006	DEVICE: BONE-LOK BIOABSORBABLE COMPRESSION ANCHOR, MODEL BMCD-35-3050S SE DECISION MADE: 27-MAR-2002 510(k) STATEMENT
U.S. FILTER/IONPURE, INC. ATTN: DAVID A DENTINO 10 TECHNOLOGY DRIVE LOWELL, MA 01851	510(k) NO: K013677 PHONE NO : 978-614-7359	DEVICE: MODIFICATION TO: MED-RO REVERSE OSMOSIS SYSTEM SE DECISION MADE: 08-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
UNIVEC, INC. ATTN: R. COHEN 22 DUBON CT. FARMINGDALE, NY 11735	510(k) NO: K020500 PHONE NO : 631-777-2000	DEVICE: UNIVEC BIFURCATED SLIDING SHEATH SYRINGE SE DECISION MADE: 19-MAR-2002 510(k) STATEMENT
UROGYN LTD. ATTN: EREZ ADIV DIAMOND BLDG.(26TH FL.) 3A JABOTINSKY ST. RAMAT-GAN,	510(k) NO: K014248 PHONE NO : 972 361 22254	DEVICE: DND 202 MANUAL UROLOGICAL DIGITAL NEEDLE DRIVER SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
VESTIL MANUFACTURING CORP. ATTN: RICH MICHAEL 900 GROWTH PARKWAY ANGOLA, IN 46703	510(k) NO: K014127 PHONE NO : 219-668-5677	DEVICE: KARMA DISCOVERY, MODEL KP40 SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
VIATRONIX, INC. ATTN: BAMAN PATTANAYAK 25 EAST LOOP RD., SUITE 204 STONY BROOK, NY 11790	510(k) NO: K020658 PHONE NO : 866-887-4636	DEVICE: VIATRONIX V3D COLON SE DECISION MADE: 07-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002

Page 32

VILEX, INC. -XX-09; VILEX SOLID BONE SCREWS DB1 THREAD,MODEL F20-XX-00 ATTN: ABRAHIM LAVI 345 OLD CURRY HOLLOW RD. PITTSBURGH, PA 15236	510(k) NO: K014154 PHONE NO : 412-655-7550	DEVICE: VILEX/DUVAL/ORTHEX CANNULATED BONE SCREW DB1 THREAD, MODEL F25 SE DECISION MADE: 18-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
VOCO GMBH ATTN: EVAN DICK 7527 WESTMORELAND AVE. ST. LOUIS, MO 63105	510(k) NO: K014111 PHONE NO : 314-721-0112	DEVICE: REBILDA SC SE DECISION MADE: 06-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WIELAND DENTAL + TECHNIK GMBH & CO ATTN: GERHARD POLZER SCHWENNINGER STRASSE 13 PFORZHEIM,	510(k) NO: K020190 PHONE NO : 49 723 13705219	DEVICE: PORTADUR P 4 SE DECISION MADE: 13-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WIELAND DENTAL + TECHNIK GMBH & CO ATTN: GERHARD POLZER SCHWENNINGER STRASSE 13 PFORZHEIM,	510(k) NO: K020192 PHONE NO : 497 231 3705219	DEVICE: SIMIDUR S2 SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WIELAND DENTAL + TECHNIK GMBH & CO ATTN: GERHARD POLZER SCHWENNINGER STRASSE 13 PFORZHEIM,	510(k) NO: K020194 PHONE NO : 49 723 13705219	DEVICE: SIMIDUR KF PLUS SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WIELAND DENTAL + TECHNIK GMBH & CO ATTN: GERHARD POLZER SCHWENNINGER STRASSE 13 PFORZHEIM,	510(k) NO: K020195 PHONE NO : 49 723 13705219	DEVICE: SIMIDUR S1S SE DECISION MADE: 15-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WOODSIDE BIOMEDICAL, INC. ATTN: CAROL PATTERSON 21911 ERIE LANE LAKE FOREST, CA 92630	510(k) NO: K020180 PHONE NO : 949-462-0900	DEVICE: RELIEFBAND DEVICE, MODELS RB-DL, RB-EL, RB-RL SE DECISION MADE: 21-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WORLD OF MEDICINE LEMKE GMBH ATTN: SUSANNE RAAB 91 TROWERIDGE STREET CAMBRIDGE, MA 02138	510(k) NO: K014158 PHONE NO : 617-868-3995	DEVICE: ENDOSCOPIC CAMERA TC804/C4 SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA
WORLD OF MEDICINE LEMKE GMBH ATTN: SUSANNE RAAB 91 TROWERIDGE STREET CAMBRIDGE, MA 02138	510(k) NO: K020336 PHONE NO : 617-868-3995	DEVICE: ENDOSCOPIC CAMERA MC404/C3 SE DECISION MADE: 14-MAR-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 33

WRIGHT MEDICAL TECHNOLOGY, INC. 510(k) NO: K014171
ATTN: EHAB M ESMAIL PHONE NO : 901-867-4732
5677 AIRLINE RD.
ARLINGTON, TN 38002

DEVICE: ADVANCE UNICONDYLAR KNEE SYSTEM
SE DECISION MADE: 15-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

XTRAK MEDICAL INC. 510(k) NO: K013473
L CONSOLE, MODEL # C10006001; XTD COLLECTION BOTTLE, MODEL
ATTN: DEBBIE IAMPIETRO PHONE NO : 508-435-9893
7 TIFFANY TRAIL
HOPKINTON, MA 01748

DEVICE: XTD THROMBECTOMY CATHETER, XX CM, MODEL# C1000500X; XTD CONTRC
SE DECISION MADE: 06-MAR-2002
510(k) SUMMARY AVAILABLE FROM FDA

XIRANA, INC. 510(k) NO: K012755
ATTN: PATRICK J O'LEARY PHONE NO : 805-654-0643
6025 NICOLE STREET
VENTURA, CA

DEVICE: AUTODIMER ASSAY MODEL # 1431
SE DECISION MADE: 15-MAR-2002
510(k) STATEMENT

ZOLL MEDICAL CORP. 510(k) NO: K011388
ATTN: PAUL DIAS PHONE NO : 781-229-0020
32 SECOND AVE.
BURLINGTON, MA 01803

DEVICE: ZOLL PAD
SE DECISION MADE: 25-MAR-2002
510(k) STATEMENT

SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALENT (SE) 510(K) SUMMARIES OR 510(K) STATEMENTS
FOR FINAL DECISIONS RENDERED DURING THE PERIOD 01-MAR-2002 THROUGH 31-MAR-2002

05-APR-2002
Page 34

TOTAL 510(k)s THIS PERIOD	289
TOTAL WITH SUMMARIES	235
TOTAL WITH STATEMENTS	54