

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

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(EMS SA) ELECTRO MEDICAL SYSTEMS
ATTN: CYNTHIA J.M. NOLTE
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760

510(k) NO: K992504
PHONE NO : 508-643-0434

DEVICE: EMS KERMIT

SE DECISION MADE: 27-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

945 '00 FEB -8 P1:51

3M CO.
ATTN: LAEL J PICKETT
3M CENTER, BLDG. 260-2B-12
ST. PAUL, MN 55144

510(k) NO: K992489
PHONE NO : 651-733-3594

DEVICE: 3M TR SYSTEM

SE DECISION MADE: 11-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

A-DEC, INC.
ATTN: PATRICK RIDENOUR
2601 CRESTVIEW DR.
NEWBERG, OR 97132-9257

510(k) NO: K993526
PHONE NO : 503-537-2756

DEVICE: SYNEA - LS LOW-SPEED HANDPIECE

SE DECISION MADE: 11-JAN-2000

510(k) STATEMENT

ACCULASE, INC.
ATTN: AL MEMMOLO
2431 IMPALA DRIVE
CARLSEAD, CA 92008

510(k) NO: K992914
PHONE NO : 760-602-3300

DEVICE: EXCIMER LASER PHOTOTHERAPY SYSTEM, AL7000

SE DECISION MADE: 27-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

ACON LABORATORIES, INC.
ATTN: NORA C.R. YORK
11175 FLINTKOTE AVE., #F & G
SAN DIEGO, CA 92121

510(k) NO: K993483
PHONE NO : 858-535-2030

DEVICE: ACON ONE STEP HOME PREGNANCY TEST STRIP

SE DECISION MADE: 20-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K993657
PHONE NO : 503-627-9957

DEVICE: ACUMED SUTURE ANCHOR

SE DECISION MADE: 13-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED REPRODUCTIVE TECHNOLOGIES
ATTN: GREG HOLLAND
3722 AVENUE SAUSALITO
IRVINE, CA 92606

510(k) NO: K991391
PHONE NO : 949-262-0411

DEVICE: PVP, POLYVINYLPIRROLIDONE 10% (W/V) IN HEPES-HITF

SE DECISION MADE: 10-JAN-2000

510(k) STATEMENT

AESCULAP, INC.
ATTN: MARY ELLEN HOLDEN
1000 GATEWAY BLVD.
SOUTH SAN FRANCISCO, CA 94080-7030

510(k) NO: K992053
PHONE NO : 650-642-5072

DEVICE: AESCULAP VASCULAR INSTRUMENTS

SE DECISION MADE: 13-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

AESCULAP, INC.
ATTN: LIA S JONES
1000 GATEWAY BLVD.
SOUTH SAN FRANCISCO, CA 94080-7030

510(k) NO: K993551
PHONE NO : 650-876-7000

DEVICE: SOCON SPINAL SYSTEM

SE DECISION MADE: 13-JAN-2000

510(k) SUMMARY AVAILABLE FROM FDA

AIRCAST, INC.
ATTN: STEPHEN KENNEY
92 RIVER RD.
SUMMIT, NJ 07902

510(k) NO: K992454
PHONE NO : 908-273-6349

DEVICE: VENAFLOW SYSTEM, MODEL 30A

SE DECISION MADE: 13-JAN-2000

510(k) STATEMENT

945-0120

LST 92

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AKTINA MEDICAL PHYSICS CORP. ATTN: JOAN ZACHAROPOULOS 360 NORTH ROUTE 9W CONGERS, NY 10920	510(k) NO: K993522 PHONE NO : 914-268-0101	DEVICE: AKTINA MEDICAL PHYSICS CORPORATION TENNIS RACQUET INSERT SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ALBERT BROWNE LTD. ATTN: CYNTHIA J.M. NOLTE 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K992767 PHONE NO : 508-643-0434	DEVICE: BROWNE PACKAGING AND LABEL STEAM PROCESS INDICATOR SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILAABLE FROM FDA
ALLEGIANCE HEALTHCARE CORP. ATTN: SHARON ROBBINS 1500 WAUKEGAN RD. MOGAW PARK, IL 60085	510(k) NO: K993795 PHONE NO : 847-785-3311	DEVICE: CONVERTORS SURGICAL DRAPES SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ALPHA OMEGA LTD. ATTN: SHOSHANA S FRIEDMN 117 AHUZAH ST. RA'ANANNA,	510(k) NO: K993622 PHONE NO : 972 771 8130	DEVICE: NEUROTREK PHYSIOLOGICAL NAVIGATION SYSTEM FOR NEUROSURGERY SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ALPHATEC MFG., INC. ATTN: JASON BLAIN 42-160 STATE ST. PALM DESERT, CA 92211-5148	510(k) NO: K993873 PHONE NO : 760-779-8250	DEVICE: ALPHATEC EXTERNAL FIXATION SYSTEM COMPRESSION/DISTRACTION ROD SE DECISION MADE: 03-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ALTATEC BIOTECHNOLOGIES ATTN: R.J. SLOMOFF 9229 CRANFORD DRIVE POTOMAC, MD 20854	510(k) NO: K000065 PHONE NO : 301-983-1707	DEVICE: CAMLOG CYLINDER IMPLANT SYSTEM SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT
ALTATEC BIOTECHNOLOGIES ATTN: R.J. SLOMOFF 9229 CRANFORD DRIVE POTOMAC, MD 20854	510(k) NO: K000099 PHONE NO : 301-983-1707	DEVICE: CAMLOG SCREW IMPLANT SYSTEM SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT
ALTATEC BIOTECHNOLOGIES ATTN: R.J. SLOMOFF 9229 CRANFORD DRIVE POTOMAC, MD 20854	510(k) NO: K000100 PHONE NO : 301-983-1707	DEVICE: CAMLOG ROOTFORM IMPLANT SYSTEM SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT
ALTHIN MEDICAL AB ATTN: LARS-OLOF SANDBERG FRIDHEMSVAGEN 15 RONNEBY,	510(k) NO: K992563 PHONE NO : 464-577-5900	DEVICE: A-22 HEMODIALYZER SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ALTHIN MEDICAL AB ATTN: LARS-OLOF SANDBERG FRIDHEMSVAGEN 15 RONNEBY,	510(k) NO: K992564 PHONE NO : 464-577-5900	DEVICE: AF-180 HEMODIALYZER SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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ALTHIN MEDICAL AB ATTN: LARS-OLOF SANDBERG FRIDHEMSVAGEN 15 RONNEBY,	510(k) NO: K992566 PHONE NO : 464-577-5900	DEVICE: AF-150 HEMODIALYZER SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ALTHIN MEDICAL AB ATTN: LARS-OLOF SANDBERG FRIDHEMSVAGEN 15 RONNEBY,	510(k) NO: K992573 PHONE NO : 464-577-5900	DEVICE: AF-220 HEMODIALYZER SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN BIO MEDICA CORP. ATTN: JOHN B DUBECK 1001 G STREET, NW SUITE 500W WASHINGTON, DC 20001	510(k) NO: K993151 PHONE NO : 202-434-4125	DEVICE: RADID DRUG SCREEN 5-PANEL TEST SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN BIO MEDICA CORP. ANNABINOIDS) AND OPIATES (3 PANEL ATTN: HENRY WELLS 122 SMITH ROAD KINDERHOOK, NY 12106	510(k) NO: K993961 PHONE NO : 800-227-1243	DEVICE: RAPID DRUG SCREEN 3-PANEL TEST FOR COCAINE, MARIJUANA (THC) (C TEST FOR CTO) SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN BIOSYSTEMS, INC. ATTN: ERIC J LARSON 20 YORKTON CT. ST. PAUL, MN 55117	510(k) NO: K993629 PHONE NO : 651-234-1211	DEVICE: ABI VEST AIRWAY CLEARANCE SYSTEM SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN TELECARE, INC. ATTN: CHARLES RICHARD ABRUSCATO 7640 GOLDEN TRIANGLE DR. EDEN PRAIRIE, MN 55344-3732	510(k) NO: K993550 PHONE NO : 612-897-0000	DEVICE: AVIVA SYSTEM, MODEL SL1010 SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
AMSINO INTL., INC. ATTN: RICHARD Y LI 833 TOWNE CENTER DR. POMONA, CA 91767	510(k) NO: K992719 PHONE NO : 909-626-3783	DEVICE: AMSURE ENTERAL DELIVERY PUMP SET WITH SPIKE SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
AMUCHINA INTL., INC. ATTN: LUDOVICO GIAVOTTO 8-8 METROPOLITAN CT. GAITHERSBURG, MD 20878	510(k) NO: K992016 PHONE NO : 301-330-7597	DEVICE: AMUKIN D SE DECISION MADE: 10-JAN-2000 510(k) STATEMENT
AMYLOR INC. ATTN: SYLVAIN DUGAS 6 ANTOINE-HENAULT NOTE-DAME OF ILE PERROT, QUEBEC,	510(k) NO: K994072 PHONE NO : 514 453 0311	DEVICE: AMYSYSTEMS PIS50CG 50 DEGREE WEIGHT SHIFT POWER TILT SYSTEM SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT

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AMYLICOR INC. FRONT-WHEEL DRIVE POWER WHEELCHAIRS. ATTN: SYLVAIN DUGAS 6 ANTOINE-HENAUULT NOTE-DAME OF ILE PERROT,QUEBEC,	510(k) NO: K994107 PHONE NO : 514 453 0311	DEVICE: AMYSYSTEMS PTS50-50 DEGREE POWER TILT SYSTEM FOR MID-WHEEL OR SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT
ANSELL PERRY INC. VES WITH PROTEIN CONTENT LABELING CLAIM (60 MICROGRAMS OR ATTN: JAMES R CHATTERTON 1875 HARSH AVENUE, S.E. MASSILLON, OH 44646-7199	510(k) NO: K993857 PHONE NO : 330-833-2811	DEVICE: THE ORIGINAL PERRY, STYLE 42 WHITE LATEX POWDERED SURGICAL GLC SE DECISION MADE: 31-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: VERNON C BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K990340 PHONE NO : 941-643-5553	DEVICE: ARTHREX PLA TISSUETAK, MODEL # AR-1940 BU SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ARTHREX, INC. ATTN: VERNON BROWN 2885 SOUTH HORSESHOE DR. NAPLES, FL 34104	510(k) NO: K990987 PHONE NO : 941-643-5553	DEVICE: BIO-ABSORBABLE CORKSCREW, MODEL AR-1920B SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ASPECT MEDICAL SYSTEMS, INC. ATTN: CHRISTINE MORGIDA 2 VISION DR. NATICK, MA 01760-2059	510(k) NO: K994330 PHONE NO : 508-653-0603	DEVICE: ASPECT MEDICAL SYSTEMS EEG SENSOR, MODEL 186-0076 SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ATRIUM MEDICAL CORP. ATTN: KAREN HALL 5 WENTWORTH DR. HUDSON, NH 03051	510(k) NO: K992991 PHONE NO : 603-880-1433	DEVICE: ATRIUM MEDICAL CORPORATION ADVANTA PTFE FACIAL IMPLANT SE DECISION MADE: 27-JAN-2000 510(k) STATEMENT
AUTOMATED OPHTHALMICS, INC. ATTN: NORMAN BICKMAN 8253 GLEMAR ROAD ELLCOTT, MD 21043	510(k) NO: K992998 PHONE NO : 800-242-5602	DEVICE: AUTOMATED OPHTHALMICS SOFTTIPS SE DECISION MADE: 10-JAN-2000 510(k) STATEMENT
AXYA MEDICAL, INC. ATTN: HOWARD L SCHRAYER 100 CUMMINGS CENTER SUITE 444C BEVERLY, MA 01915	510(k) NO: K994313 PHONE NO : 609-924-9510	DEVICE: MODIFICATION TO BONE ANCHOR AND KIT (BAK) SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
B. BRAUN/MCGAW ATTN: VALERIE LEWIS 901 MARCON BLVD. ALLENTOWN, PA 18103-9341	510(k) NO: K994111 PHONE NO : 610-266-0500	DEVICE: CELSITE, MODELS ST401L, ST405L SE DECISION MADE: 03-JAN-2000 510(k) STATEMENT

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BAUSCH & LOMB, INC. ATTN: VANADA JOHNSON 3365 TREE COURT INDUSTRIAL BLV ST. LOUIS, MO 63122-6694	510(k) NO: K993039 PHONE NO : 636-226-3182	DEVICE: VISCOUS FLUID INJECTOR SYSTEM MODULE (CX5700) SE DECISION MADE: 07-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: MICHEL GUST 1000 LAKE HAZELTINE DR. CHASKA, MN 55318-1084	510(k) NO: K993210 PHONE NO : 612-368-7688	DEVICE: ACCESS HYBRITTECH FREE PSA QC, MODEL 37219 SE DECISION MADE: 05-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: LUCINDA STOCKERT 200 SOUTH KRAEMER BLVD., W-337 BREA, CA 92822-8000	510(k) NO: K993954 PHONE NO : 714-961-3777	DEVICE: SYNCHRON SYSTEMS DAT MULTI-DRUG LOW AND HIGH URINE CALIBRATORS SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: MICHELE GUST 1000 LAKE HAZELTINE DR. CHASKA, MN 55318-1084	510(k) NO: K994200 PHONE NO : 612-368-7688	DEVICE: ACCESS HYBRITTECH PSA QC, MODEL 37209 SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: MARA CALER 7330 CARROLL ROAD SAD DIEGO, CA 92196-9006	510(k) NO: K994277 PHONE NO : 858-621-4583	DEVICE: ACCESS OSTASE QC SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. ATTN: GAIL LEFEBVRE 200 S. KRAEMER BLVD., W-104 BREA, CA 92822-8000	510(k) NO: K994325 PHONE NO : 714-993-8503	DEVICE: SYNCHRON CX SYSTEMS MICROALBUMIN CALIBRATOR SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC. 33305, 33309, 33306 ATTN: MICHELE S GUST 1000 LAKE HAZELTINE DR. CHASKA, MN 55318-1084	510(k) NO: K994439 PHONE NO : 612-368-7688	DEVICE: ACCESS CK-MB ON THE ACCESS IMMUNOASSAY ANALYZER, MODELS 33300, SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BELMONT INSTRUMENT CORP. ATTN: URAIWAN P LABADINI 780 BOSTON RD. BILLERICA, MA 01821	510(k) NO: K983866 PHONE NO : 978-663-0212	DEVICE: BELMONT MODEL NGPBP INTRA-AORTIC BALLOON PUMP SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BESGLOVE MEDICARE SDN. BHD. CROGRAM OR LESS) ATTN: LEE AIK LIM LOT 6, JALAN P/2A BANGI INDUSTRIAL ESTATE KAJANG, SELANGOR DARUL, EHASAN,	510(k) NO: K994082 PHONE NO : 603 825 6361	DEVICE: POWDERED LATEX EXAMINATION GLOVES (PROTEIN LABEL CLAIM) (50 MI SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT

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BICON, INC. ATTN: VINCENT J MORGAN 1153 CENTRE STREET BOSTON, MA 02130	510(k) NO: K994037 PHONE NO : 617-524-4443	DEVICE: THE 4.5MM DIAMETER BICON DENTAL IMPLANT SE DECISION MADE: 11-JAN-2000 510(k) STATEMENT
BIOCOMPOSITES LTD. ATTN: JS BRATT ETRUSCAN ST., ETRURIA STOKE ON TRENT,	510(k) NO: K993238 PHONE NO : 44 178 2206500	DEVICE: FORTOSS-CEMA SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BIOHORIZONS IMPLANT SYSTEMS, INC. ATTN: WINSTON D GREER ONE PERIMETER PARK SOUTH SUITE 230, SOUTH BIRMINGHAM, AL 35243	510(k) NO: K993493 PHONE NO : 205-967-7880	DEVICE: THE AUTOTAC SYSTEM SE DECISION MADE: 07-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BIOMERIDIAN, INC. ATTN: JOE GALLOWAY 12411 SOUTH 265 WEST SUITE F DRAPER, UT 84020	510(k) NO: K993824 PHONE NO : 801-501-7517	DEVICE: MSA-21 SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET MANUFACTURING, INC. ATTN: TRACY J BICKEL AIRPORT INDUSTRIAL PARK P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K994326 PHONE NO : 219-372-1761	DEVICE: ASCENT KNEE SYSTEM SE DECISION MADE: 07-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BIOPRO (M) SDN BHD ATTN: JAMES H LALE LOT14, PT.4204 LINGKARN SULTAN HISHAMUDDIN, NORTH PORT INDU. PORT KLANG,	510(k) NO: K994043 PHONE NO : 603 376 1390	DEVICE: CORRECT TOUCH LATEX POWDERED EXAMINATION GLOVES SE DECISION MADE: 11-JAN-2000 510(k) STATEMENT
BIOSURGICAL CORP. E-1 ATTN: TERRY LAAS 5990 STONERIDGE DRIVE SUITE 112 PLEASANTON, CA 94555	510(k) NO: K000048 PHONE NO : 925-737-1850	DEVICE: SEALOQUETTE FIBRIN SEALANT EXTENDED DROPLET APPLICATOR, MODEL T SE DECISION MADE: 31-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BIRD PRODUCTS CORP. ATTN: TOM GUTIERREZ 1100 BIRD CENTER DR. PALM SPRINGS, CA 92262	510(k) NO: K990856 PHONE NO : 760-778-7255	DEVICE: HERITAGE NASAL CPAP SYSTEM, MODEL P/N 15682 SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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BOSTON SCIENTIFIC CORP. ATTN: ANDREA BOUMIS 2710 ORCHARD PKWY. SAN JOSE, CA 95113	510(k) NO: K994252 PHONE NO : 408-895-3625	DEVICE: INTRODUCER SHEATHS, VESSEL DILATOR, GUIDEWIRE SE DECISION MADE: 04-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC, TARGET LAMEETER STRETCH RESISTANT GUGLIELMI DETACHABLE COIL, GDC-1 ATTN: ROXANE BAXTER 47900 BAYSIDE PARKWAY FREMONT, CA 94538	510(k) NO: K993415 PHONE NO : 510-624-2105	DEVICE: GDC-10 STRETCH RESISTANT GUGLIELMI DETACHABLE COIL, GDC-10 2-D SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC, TARGET GUGLIELMI DETACHABLE COIL (GDC) (3D SHAPE GDC) ATTN: ROXANE BAXTER 47900 BAYSIDE PARKWAY FREMONT, CA 94538	510(k) NO: K993417 PHONE NO : 510-624-2105	DEVICE: GDC-10 GUGLIELMI DETACHABLE COIL (GDC) (3D SHAPE GDC), GDC-18 SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC, TARGET ATTN: ROXANE BAXTER 47900 BAYSIDE PARKWAY FREMONT, CA 94538	510(k) NO: K993418 PHONE NO : 510-624-2105	DEVICE: FIBERED GDC-18 VORTX SHAPE GUGLIELMI DETACHABLE COIL SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BRAINLAB ATTN: ERIC LINDQUIST 100 MARINE PARKWAY SUITE 305 REDWOOD CITY, CA 94065	510(k) NO: K992916 PHONE NO : 650-494-7240	DEVICE: BRAINLAB STEREOCTACTIC ARC SE DECISION MADE: 11-JAN-2000 510(k) STATEMENT
BRONCUS TECHNOLOGIES, INC. ODEL 20-115 ATTN: JOHN D'ANGELO 1400N SHORELINE BLVD. BLDG. A, SUITE 8 MOUNTAIN VIEW, CA 94043	510(k) NO: K993900 PHONE NO : 650-428-1600	DEVICE: COAGULATION ELECTRODE, MODEL 2000; RADIOFREQUENCY GENERATOR, M SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
BUMEDCO INTL., INC. ATTN: DARROLD GLANVILLE 725 TIMBER LANE SHOREVIEW, MN 55126	510(k) NO: K984083 PHONE NO : 651-787-0625	DEVICE: MULTIFUNCTION KEITO K5 SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. ATTN: CAROL VIERLING 13183 HARLAND DR. COVINGTON, GA 30014	510(k) NO: K993392 PHONE NO : 770-385-2347	DEVICE: BARD MEMOTHERM FLEXX BILIARY STENT SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. ATTN: ANGELA L BUNN 8195 INDUSTRIAL BLVD. COVINGTON, GA 30209	510(k) NO: K993840 PHONE NO : 770-784-6774	DEVICE: BARD UROFORCE BALLOON DILATION CATHETER SE DECISION MADE: 31-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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C.R. BARD, INC. URAGLIDE STONE BALLOON, MODEL 007124-25,007144-45 ATTN: MARION GORDON 129 CONCORD RD., BLDG. 3 BILLERICA, MA 01821-7031	510(k) NO: K993892 PHONE NO : 978-262-4867	DEVICE: DURAGLIDE STONE REMOVAL BALLOON, MODEL 000635-38, 000646-47, D SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CANDELA CORP. ATTN: JOAN CLIFFORD 530 BOSTON POST RD. WAYLAND, MA 01778	510(k) NO: K993671 PHONE NO : 508-358-7637	DEVICE: CANDELA SCLERO LONG PULSE DYE LASER SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CARADYNE, LTD. ATTN: PAUL E DRYDEN 6329 W. WATERVIEW CT. MCCORDSVILLE, IN 46055	510(k) NO: K992101 PHONE NO : 317-335-3780	DEVICE: CRITERION 40 OR PM 40 SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CARDIAC SCIENCE, INC. ATTN: STAN E TILLMAN 16931 MILLIKAN AVE. IRVINE, CA 92606	510(k) NO: K993533 PHONE NO : 949-587-0357	DEVICE: POWERHEART AECD SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CARDIOVASCULAR DIAGNOSTICS, INC. ON TEST, RAPIDPOINT COAG PROTAMINE RESPONSE TEST ATTN: PETER SCOTT 5301 DEPARTURE DR. RALEIGH, NC 27616	510(k) NO: K993519 PHONE NO : 919-874-6103	DEVICE: RAPIDPOINT ACCENT, MODEL 2000, RAPIDPOINT COAG HEPARIN TITRATI SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CASE MEDICAL, INC. INER SYSTEM WITH SCF02 - POLYPROPYLENE NON-WOVEN DISPOSABL ATTN: LARRY R PILOT 1900 K STREET, N.W. WASHINGTON, DC 20006-1108	510(k) NO: K991023 PHONE NO : 202-496-7561	DEVICE: STERITITE PERFORATED BOTTOM RIGID REUSABLE STERILIZATION CONTA SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CIBA VISION CORP. ATTN: STEVEN DOWDLEY 11460 JOHNS CREEK PKWY. DULUTH, GA 30097	510(k) NO: K993949 PHONE NO : 770-418-3897	DEVICE: SOLO-CARE BRAND HARD SOLUTION SE DECISION MADE: 05-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CONTEXTIVISION AB ATTN: CONSTANCE BUNDY 6470 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	510(k) NO: K993802 PHONE NO : 612-574-1976	DEVICE: SHARPVVIEW IMAGE ENHANCEMENT SYSTEM SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
COCK BIOTECH, INC. ATTN: NEAL E FEARNOT 3055 KENT AVE. WEST LAFAYETTE, IN 47906-1076	510(k) NO: K993948 PHONE NO : 765-497-3355	DEVICE: SIS WOUND DRESSING II SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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COOK, INC. ATTN: KAREN BRADEBURN 925 S. CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K993455 PHONE NO : 800-346-2686	DEVICE: FLIPPER DETACHABLE EMBOLIZATION COIL SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: ARIEL MACTAVISH 14201 N.W. 60TH AVE. MIAMI LAKES, FL 33014	510(k) NO: K993720 PHONE NO : 305-824-2332	DEVICE: CORDIS MAXI LD LARGE DIAMETER BALLOON DILATATION CATHETER SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. RY STENT, MODELS PQ294B, PQ394B ATTN: CHARLES J RYAN 7 POWDERHORN DRIVE WARREN, NJ 07059	510(k) NO: K994156 PHONE NO : 908-412-7446	DEVICE: MODIFICATION TO CORDIS PALMAZ CORINTHIAN IQ TRANSHEPATIC BILLIA SE DECISION MADE: 07-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. ATTN: DENNIS S GRIFFIN 14201 N.W. 60TH AVE. MIAMI LAKES, FL 33014	510(k) NO: K994358 PHONE NO : 305-824-5283	DEVICE: ATW MARKER WIRE STEERABLE GUIDEWIRE SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
COSMEDENT, INC. ATTN: MICHAEL O'MALLEY 5419 NORTH SHERIDAN RD. CHICAGO, IL 60640	510(k) NO: K993658 PHONE NO : 773-989-6844	DEVICE: RENAMEL SCULPT SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
COSMEDENT, INC. ATTN: MICHAEL O'MALLEY 5419 NORTH SHERIDAN RD. CHICAGO, IL 60640	510(k) NO: K993659 PHONE NO : 773-989-6844	DEVICE: RENAMEL PACK SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
CUSTOM ASSEMBLIES, INC. ATTN: PAUL E DRYDEN 6329 W. WATERVIEW CT. MCCORDSVILLE, IN 46055	510(k) NO: K993463 PHONE NO : 317-335-3780	DEVICE: INTRAVASCULAR ADMINISTRATION SET SE DECISION MADE: 04-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CYNOSURE, INC. ATTN: GEORGE CHO 10 ELIZABETH DR. CHELMSFORD, MA 01824	510(k) NO: K994427 PHONE NO : 978-256-4200	DEVICE: CYNOSURE M2 DERMATOLOGY LASER FOR HAIR REMOVAL SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
CYNOSURE, INC. ATTN: GEORGE CHO 10 ELIZABETH DR. CHELMSFORD, MA 01824	510(k) NO: K994437 PHONE NO : 978-256-4200	DEVICE: CYNOSURE PHOTOGENICA SPIR SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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DADE BEHRING, INC. ATTN: REBECCA S AYASH GLASGOW SITE P.O. BOX 6101 NEWARK, DE 19714	510(k) NO: K992957 PHONE NO : 302-631-6276	DEVICE: ADVANCED D-DIMER SE DECISION MADE: 28-JAN-2000 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: K992959 PHONE NO : 302-631-6276	DEVICE: BEHRING COAGULATION SYSTEM (BCS) SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: ROBIN O NORRIS P.O. BOX 6101 GLASGOW BLDG. 500 NEWARK, DE 19714-6101	510(k) NO: K994114 PHONE NO : 302-631-7446	DEVICE: DIMENSION TOTAL IRON BINDING CAPACITY (IBCT) CALIBRATOR SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: ROBIN O NORRIS BLDG. 500 MAIL BOX 514 P.O. BOX 6101 NEWARK, DE 19714-6101	510(k) NO: K994115 PHONE NO : 302-631-7446	DEVICE: TOTAL IRON BINDING CAPACITY (IBCT) FLEX REAGENT CARTRIDGE SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DADE MICROSCAN, INC. ATTN: SHAROLYN J LEVITSCH 1584 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K983953 PHONE NO : 916-374-8183	DEVICE: MICROSTREP PLUS PANEL, VANCOMYCIN SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DADE MICROSCAN, INC. ATTN: TREVOR WALL 2040 ENTERPRISE BLVD. WEST SACRAMENTO, CA 95691	510(k) NO: K993679 PHONE NO : 916-374-3222	DEVICE: MICROSTREP PLUS PANEL - HAEMOPHILUS/AMPICILLIN SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DATASCOPE CORP. ATTN: SUSAN E MANDY 580 WINTERS AVENUE PARAMUS, NJ 07652	510(k) NO: K993531 PHONE NO : 201-967-2229	DEVICE: PASSPORT 2 VITAL SIGNS MONITOR, MODEL 0998-00-0170-XX SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DEGUSSA - NEY DENTAL, INC. ATTN: ANDREW J PIETROBONO 1065 S.W. 30TH AVE. DEERFIELD BEACH, FL 33442-8193	510(k) NO: K993897 PHONE NO : 954-429-2886	DEVICE: CERGOGOLD SE DECISION MADE: 10-JAN-2000 510(k) STATEMENT
DEPUY, INC. ATTN: ARLENE C SAULL 700 ORTHOPAEDIC DR. P.O. BOX 988 WARSAW, IN 46581-0988	510(k) NO: K993465 PHONE NO : 219-371-4904	DEVICE: DEPUY ACE CALCANEAL PERI-ARTICULAR PLATE SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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DIAGNOSTIC CHEMICALS LTD. ATTN: KAREN CALLEBECK 16 MCCARVILLE STREET WEST ROYALTY INDUSTRIAL PARK CHARLOTTE TOWN, P.E.I.,	510(k) NO: K993920 PHONE NO : 902 566 1396	DEVICE: ETHANOL-L3K ASSAY, CATALOGUE NUMBER 273-30, 273-17 SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
DIAGNOSTIC PRODUCTS CORP. ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K992632 PHONE NO : 310-645-8200	DEVICE: IMMULITE AMPHETAMINE, MODELS LKAM1, LKAM5 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTIC PRODUCTS CORP. ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K992634 PHONE NO : 310-645-8200	DEVICE: IMMULITE METHAMPHETAMINE, MODEL LKMA1, LKMA5 SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTIC PRODUCTS CORP. ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K994085 PHONE NO : 310-645-8200	DEVICE: IMMULITE TURBO HCG, MODELS LSKCG1, LSKCG5 SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DISPOS-A-SCOPE ATTN: LAUREL NICHOLAS 315 SKYLINE DRIVE LEWISTON, ID 83501	510(k) NO: K993738 PHONE NO : 208-743-4567	DEVICE: DISPOS-A-SCOPE SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
DYNATRONICS CORP. ATTN: JOHN S RAMSEY 7030 PARK CENTRE DR. SALT LAKE CITY, UT 84121	510(k) NO: K993919 PHONE NO : 801-568-7000	DEVICE: DYNATRON 900 SE DECISION MADE: 03-JAN-2000 510(k) STATEMENT
ENCORE ORTHOPEDICS, INC. ATTN: DEBBIE DE LOS SANTOS 9800 METRIC BLVD. AUSTIN, TX 78758	510(k) NO: K994070 PHONE NO : 512-834-6237	DEVICE: REVELATION POROUS HIP STEM SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ENDOCARDIAL SOLUTIONS, INC. ATTN: JAMES BULLOCK 1350 ENERGY LN., SUITE 110 ST. PAUL, MN 55108	510(k) NO: K993376 PHONE NO : 651-523-6928	DEVICE: ENSTYLET MODELS ECO010, ECO020 SE DECISION MADE: 05-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ENIHERMICS MEDICAL SYSTEMS, INC. ATTN: EMALIE G MURPHY 1900 K STREET NW WASHINGTON, DC 20006-1108	510(k) NO: K993797 PHONE NO : 202-496-7255	DEVICE: EC-7701 FLUID WARMING CABINET SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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EPIC MEDICAL EQUIPMENT SERVICES IN510(k) NO: K992811 G ATTN: KRISTA OAKES 1800 10TH ST., SUITE 300 PLANO, TX 75074	PHONE NO : 972-801-9854	DEVICE: TRANSDUCERS FOR ULTRASOUND AND TOCODYNAMOMETER FETAL MONITORIN SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ESC MEDICAL SYSTEMS LTD. ATTN: ZVI LADIN 250 FIRST AVENUE NEEDHAM, MA 02194	510(k) NO: K991935 PHONE NO : 781-444-8446	DEVICE: EPILIGHT HAIR REMOVAL SYSTEM, PHOTODERM HR SYSTEM SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ESPE DENTAL AG ATTN: ANDRERAS PETERMANN ESPE PLATZ SEEFELD, BAVARIA,	510(k) NO: K994190 PHONE NO : 011 498 152700139	DEVICE: IMPREGUM GARANT L DUOSOFT SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ESPE DENTAL AG ATTN: ANDREAS PETERMANN ESPE PLATZ SEEFELD, BAVARIA,	510(k) NO: K994192 PHONE NO : 011 498 152700139	DEVICE: IMPREGUM PENTIA M MONOSOFT SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ESPE DENTAL AG ATTN: ANDREAS PETERMANN ESPE PLATZ SEEFELD, BAVARIA,	510(k) NO: K994193 PHONE NO : 011 498 152700139	DEVICE: IMPREGUM PENTIA DUOSOFT SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ESPE DENTAL AG ATTN: ANDREAS PETERMANN ESPE PLATZ SEEFELD, BAVARIA,	510(k) NO: K994251 PHONE NO : 011 498 152700139	DEVICE: KETAC-MOLAR QUICK SE DECISION MADE: 03-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ETHICON, INC. ATTN: GREGORY JONES P.O. BOX 151, ROUTE 22 SOMERVILLE, NJ 08876	510(k) NO: K994418 PHONE NO : 908-218-2481	DEVICE: VERSAPOINT ELECTROSURGERY SYSTEM (SCUBA) SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
EXACTECH, INC. COMPONENT ATTN: GARY J MILLER 2320 N.W. 66TH CT. GAINESVILLE, FL 32653	510(k) NO: K993736 PHONE NO : 352-377-1140	DEVICE: EXACTECH ACUMATCH INTEGRATED HIP SYSTEM M-SERIES FEMORAL STEM SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
FACTOR, II, INC. ATTN: JOHN D MCFALL 1972 FOREST AVE. LAKESIDE, AZ 85929	510(k) NO: K984297 PHONE NO : 520-537-8387	DEVICE: MAGNA ABUTMENT SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT

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FAS MEDICAL LTD.
ATTN: LYNNE ARONSON
PO BOX 219
INDIAN HILLS, CO 80454

510(k) NO: K993614
PHONE NO : 303-697-8198

DEVICE: FAS ENDOLUMINAL BRUSH
SE DECISION MADE: 18-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

FLEXITECH SDN. BHD.
TEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)
ATTN: Y. F HEW
LOT 5071, BATU 5 1/2, JALAN
MERU
KLANG, SELANGOR,

510(k) NO: K994354
PHONE NO : 603 392 0188

DEVICE: POLYMER COATED, POWDER FREE, LATEX EXAMINATION GLOVES WITH PRC
SE DECISION MADE: 31-JAN-2000
510(k) STATEMENT

FOREFRONT DIAGNOSTICS, INC.
TI-DRUG THC/COC/MET TEST, MODEL 330C; INSTACHECK MULTI-DRUG
ATTN: FENG-YU LEE
23561 RIDGE ROUTE DR., SUITE D
LAGUNA HILLS, CA 92653

510(k) NO: K993863
PHONE NO : 949-595-0673

DEVICE: INSTACHECK MULTI-DRUG THC/COC TEST, MODEL 200C; INSTACHECK MUL
SE DECISION MADE: 27-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

FRIADENT GMBH
ATTN: CAROL PATTERSON
21911 ERIE LANE
LAKE FOREST, CA 92630

510(k) NO: K993560
PHONE NO : 949-462-0900

DEVICE: FRIALIT-2 BONE PROFILER
SE DECISION MADE: 10-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

GAMERO HEALTHCARE
ATTN: JEFFREY R SHIDEMAN
1185 OAK ST.
LAKEWOOD, CO 80215-4498

510(k) NO: K990039
PHONE NO : 612-835-4018

DEVICE: GAMERO DQM 200
SE DECISION MADE: 27-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

GAMMA MEDICA
ATTN: BRADLEY E PAIT
19355 BUSINESS CENTER DR.,
SUITE 8
NORTHRIDGE, CA 91324

510(k) NO: K993813
PHONE NO : 818-709-2468

DEVICE: LUMAGEM SCINTILLATION CAMERA
SE DECISION MADE: 18-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

GC AMERICA, INC.
ATTN: TERRY L JORITZ
3737 WEST 127TH ST.
CHICAGO, IL 60658

510(k) NO: K993973
PHONE NO : 708-597-0900

DEVICE: FUJI II LC CAPSULE
SE DECISION MADE: 11-JAN-2000
510(k) STATEMENT

GC AMERICA, INC.
ATTN: TERRY L JORITZ
3737 WEST 127TH ST.
CHICAGO, IL 60658

510(k) NO: K994077
PHONE NO : 708-597-0900

DEVICE: AROMA FINE (NORMAL AND FAST SET)
SE DECISION MADE: 27-JAN-2000
510(k) STATEMENT

GDS TECHNOLOGY, INC.
ATTN: KEITH CRAWFORD
25235 LEER DRIVE
P.O. BOX 473
ELKHART, IN 46515

510(k) NO: K994073
PHONE NO : 219-264-7384

DEVICE: HEMOSITE TEST SYSTEM
SE DECISION MADE: 14-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

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GENERAL AIR SERVICE AND SUPPLY ATTN: MICHAEL FISHER 6330 COLORADO BLVD. COMMERCE CITY, CO 80022	510(k) NO: K993789 PHONE NO : 303-892-7003	DEVICE: CLINICAL BLOOD GAS MIXTURE SE DECISION MADE: 10-JAN-2000 510(k) STATEMENT
GENESIS MEDICAL, INC. ATTN: THOMAS WEHMAN 524 WEDDEL DRIVE, SUITE 4 SUNNYVALE, CA 94089	510(k) NO: K992045 PHONE NO : 408-522-8690	DEVICE: ELECTROSURGICAL ELECTRODE FAMILY SE DECISION MADE: 27-JAN-2000 510(k) STATEMENT
GLOVCO (M) SDN. BHD. G CLAIM (100 MICROGRAMS OR LESS) ATTN: TAN CHWEE HOCK LOT 760, JALAN HAJI SIRAT, OFF JALAN MERU KLANG, SELANGOR D.E.,	510(k) NO: K994013 PHONE NO : 603 391 3888	DEVICE: POWDERED LATEX EXAMINATION GLOVES WITH PROTEIN CONTENT LABELIN SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
GLOVE SOURCE, INC. ATTN: EMMY TJOENG 889 SOUTH AZUSA AVE. CITY OF INDUSTRY, CA 91748	510(k) NO: K994064 PHONE NO : 626-913-1798	DEVICE: BLUE NITRILE EXAMINATION GLOVES - POWDER FREE SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
GREGORY S. JACOB, D.D.S. ATTN: GREGORY S JACOB 9672 READING CIRCLE DES PLAINS, IL 60016	510(k) NO: K994048 PHONE NO : 847-298-8954	DEVICE: PORTABLE LIGHT CURING UNIT SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT
GROUPE LEPINE ATTN: DOUGLAS W STUART 962 SOUTH TAMiami TRAIL SUITE 203 SARASOTA, FL 34326	510(k) NO: K991962 PHONE NO : 941-366-1882	DEVICE: EIS DYNAMIC MEMORY STAPLES SYSTEM SE DECISION MADE: 10-JAN-2000 510(k) STATEMENT
GUIDANT CORP. ERIPHERAL DILATATION CATHETER ATTN: SUSAN SILAVIN 3200 LAKESIDE DR. P.O. BOX 58167 SANTA CLARA, CA 95054-2807	510(k) NO: K993639 PHONE NO : 408-235-3127	DEVICE: RX VIATRAC 18 PERIPHERAL DILATATION CATHETER, OTW VIATRAC 18 P SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
GUTHRIE MEDICARE PRODUCTS (NS) ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD., SUITE 200 GREAT NECK, NY 11021	SDN510(k) NO: K993793 PHONE NO : 203-431-1511	DEVICE: GUTHRIE PRIME PRE-POWDERED PATIENT LATEX EXAMINATION GLOVE SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
GYNECARE, INC. ATTN: GREGORY JONES P.O. BOX 151 SOMMERVILLE, NJ 08876-0151	510(k) NO: K992901 PHONE NO : 908-218-2481	DEVICE: GYNECARE VERSAPOINT G-VAP ELECTRODE SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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HARDY DIAGNOSTICS ATTN: MELISSA M TRAYLOR 1430 WEST MCCOY LANE SANTA MARIA, CA 93455	510(k) NO: K994051 PHONE NO : 805-346-2766	DEVICE: HARDYDISK DOXYCYCLINE, 30MCG SE DECISION MADE: 10-JAN-2000 510(k) STATEMENT
HARDY DIAGNOSTICS ATTN: MELISSA M TRAYLOR 1430 WEST MCCOY LANE SANTA MARIA, CA 93455	510(k) NO: K994063 PHONE NO : 805-346-2766	DEVICE: HARDYDISK AZTREONAM, 30MCG SE DECISION MADE: 14-JAN-2000 510(k) STATEMENT
HARDY DIAGNOSTICS ATTN: MELISSA M TRAYLOR 1430 WEST MCCOY LANE SANTA MARIA, CA 93455	510(k) NO: K994067 PHONE NO : 805-346-2766	DEVICE: HARDY DISK AMPICILLIN/SULBACTAM SE DECISION MADE: 14-JAN-2000 510(k) STATEMENT
HARDY DIAGNOSTICS ATTN: MELISSA M TRAYLOR 1430 WEST MCCOY LANE SANTA MARIA, CA 93455	510(k) NO: K994132 PHONE NO : 805-346-2766	DEVICE: HARDYDISK IMIPENEM, 10MCG SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
HEWLETT-PACKARD CO. ATTN: MIKE HUDON 3000 MINUTEMAN RD. ANDOVER, MA 01810-1085	510(k) NO: K993587 PHONE NO : 978-659-3173	DEVICE: HP M2376A DEVICE LINK SYSTEM SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
HEWLETT-PACKARD GMBH ONITOR M3000A/M3046A/M3016A,REL B ATTN: EGON PFEIL HERREBERGER STR. 110-140 BOEELINGEN,	510(k) NO: K992273 PHONE NO : 703-114-2243	DEVICE: HP VIRIDIA MULTI-MEASUREMENT SERVER/COMPACT PORTABLE PATIENT M SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: JENNIFER A DAUDELIN 359 VETERANS BLVD. RUTHERFORD, NJ 07070-2584	510(k) NO: K993768 PHONE NO : 201-507-7283	DEVICE: CITATION TMZF HA STEM SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
HUNLEIGH HEALTHCARE, INC. ATTN: AUDREY A WITCO 227 RT. 33 EAST MANALAPAN, NJ 07726-8362	510(k) NO: K990569 PHONE NO :	DEVICE: BABY DOPPLEX 4000, MODEL BD 4000 SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
HURRICANE MEDICAL ATTN: DAVID A CLAPP 2331K 63RD AVE. EAST BRADENTON, FL 34203	510(k) NO: K993361 PHONE NO : 941-751-0588	DEVICE: TUBING EXTENSION SET SE DECISION MADE: 04-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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ICON INFL., LLC. ATTN: GERALD S AUSLANDER 300 OZARK TRAIL DRIVE #207C ELLISVILLE, MO 63011	510(k) NO: K993461 PHONE NO : 636-527-2707	DEVICE: QUEST INTERSEGMENTAL ROLLER TRACTION TABLE SE DECISION MADE: 03-JAN-2000 510(k) STATEMENT
ILIFE SYSTEMS, INC. ATTN: JOSHUA A ADLER 5910 NORTH CENTRAL EXPRESSWAY SUITE 1775 DALLAS, TX 75206	510(k) NO: K991087 PHONE NO : 214-365-7400	DEVICE: HANNAH WIRELESS VITAL SIGNS MONITOR SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILAABLE FROM FDA
IMAGE-GUIDED NEUROLOGICS, INC. ATTN: DAVID M LEE 2290 W. EAU GALLIE BLVD SUITE 210 MELBOURNE, FL 32935	510(k) NO: K993682 PHONE NO : 407-757-8990	DEVICE: MRI EQUIPMENT COVER SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
INDUSTRIELLE ENWICKLUNG MEDIZINTE ATTN: GUENTER GINSBERG 11641 RED HIBISCUS DRIVE BONITA SPRINGS, FL 34135	510(k) NO: K991545 PHONE NO : 941-948-2001	DEVICE: WATCH STYLE WRIST DIGITAL BLOOD PRESSURE MONITOR, MODEL: KLOCK SE DECISION MADE: 19-JAN-2000 510(k) STATEMENT
INFRA-MED TECHNOLOGIES, INC. ATTN: BERTRAM J HUDSON 3535 FIREWHEEL DRIVE, SUITE A FLOWER MOUND, TX 75028-2628	510(k) NO: K992258 PHONE NO : 972-355-9700	DEVICE: HOT SHOT FLUID WARMER IV FLUIDS SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
INNOVASIVE DEVICES, INC. ATTN: KATHLEEN MORAHAN 734 FOREST ST. MARLBOROUGH, MA 01752	510(k) NO: K994269 PHONE NO : 508-460-8229	DEVICE: TITAN RC TACK SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILAABLE FROM FDA
INNOVATIVE GLOVES CO; LTD TEIN LABELING CLAIM [50 MICROGRAMS OR LESS] ATTN: RAJEEV KUMAR SOOD 11 CHOTEVITTAYAKUL 3 ROAD KHONG, HATYAI, SONGKHLA,	510(k) NO: K993567 PHONE NO : 667 442 8408	DEVICE: INNOVATIVE GLOVES LATEX EXAMINATION GLOVES POWDERFREE WITH PRC SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
INOVA DIAGNOSTICS, INC. ATTN: GARY L NORMAN 10180 SCRIPPS RANCH BLVD. SAN DIEGO, CA 92131	510(k) NO: K994004 PHONE NO : 619-586-9900	DEVICE: QUANTA LITE LYME B. BURGENDORFERI IGG/IGM ELISA KIT SE DECISION MADE: 27-JAN-2000 510(k) STATEMENT
INSTRUMENTATION INDUSTRIES, INC. ATTN: TRICIA WOOD 2990 INDUSTRIAL BLVD. BETHEL PARK, PA 15102	510(k) NO: K991355 PHONE NO : 412-854-1133	DEVICE: METERED DOSE INHALER ADAPTER-DISPOSABLE, ADAPTER REUSABLE SE DECISION MADE: 27-JAN-2000 510(k) STATEMENT

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INTER-OS TECHNOLOGIES, L.L.C. 510(k) NO: K993869
ATTN: RANDOLPH C ROBINSON PHONE NO : 303-699-7970
7144 S. CHAPPARAL CIR. E.
AURORA, CO 80016

DEVICE: INTER-OS BONE GENERATOR
SE DECISION MADE: 19-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

INTERCONTINENTAL NEW TECHNOLOGIES, 510(k) NO: K992256
ATTN: DANIEL KAMM PHONE NO : 847-374-1727
PO BOX 7007
DEERFIELD, IL 60015

DEVICE: FROLOV'S RESPIRATION TRAINING DEVICE, FRID-01
SE DECISION MADE: 11-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

INTERNATIONAL BIOPHYSICS CORP. 510(k) NO: K992785
ATTN: H. DAVID SHOCKLEY, JR PHONE NO : 512-326-3244
4020 SOUTH INDUSTRIAL DR.
SUITE 160
AUSTIN, TX 78744

DEVICE: IBC FLOGUARD, MODEL 6050
SE DECISION MADE: 14-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

INTERNATIONAL NEWTECH DEVELOPMENT, 510(k) NO: K993850
ATTN: DENNIS S.L. HONG PHONE NO : 604 522 1619
1629 FOSTERS WAY
DELTA, B.C.,

DEVICE: URINALYSIS REAGENT STRIPS (10 PARAMETERS)
SE DECISION MADE: 03-JAN-2000
510(k) STATEMENT

ISOPURE CORP. 510(k) NO: K993200
ATTN: KEVIN C GILLESPIE PHONE NO : 502-267-7873
11700 COMMONWEALTH DRIVE
SUITE 605
LOUISVILLE, KY 40299

DEVICE: MD 420/440/460/470/480/490
SE DECISION MADE: 24-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

J. MORITA USA, INC. 510(k) NO: K992648
ATTN: KEITH A BARRITT PHONE NO : 202-783-5070
601 13TH STREET, N.W.
SUITE 500 NORTH
WASHINGTON, DC 20005

DEVICE: ROTARY MASTER
SE DECISION MADE: 31-JAN-2000
510(k) STATEMENT

K-JUMP HEALTH CO., LTD. 510(k) NO: K984551
ATTN: JONATHAN S KAHAN PHONE NO : 202-637-5794
555 THIRTEEN STREET, N.W.
WASHINGTON, DC 20004-1109

DEVICE: INFRARED EAR THERMOMETER, MODEL KI-8120
SE DECISION MADE: 14-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

KINETIC CONCEPTS, INC. 510(k) NO: K992448
ATTN: JUDITH A HARBOUR PHONE NO : 210-255-4468
P.O. BOX 659508
SAN ANTONIO, TX 78265

DEVICE: V.A.C. PLUS
SE DECISION MADE: 18-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

LASER DENTAL INNOVATIONS 510(k) NO: K993942
ATTN: DAVID W SCHLERF PHONE NO : 925-356-2640
200 GREGORY LANE
SUITE C-100
PLEASANT HILL, CA 94523

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

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LASERSIGHT TECHNOLOGIES, INC. ATTN: MICHAEL P DAYTON 3300 UNIVERSITY BLVD., #140 WINTER PARK, FL 32792	510(k) NO: K990227 PHONE NO : 407-678-9900	DEVICE: ULTRASHAPER KERATOME SE DECISION MADE: 31-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
LOKKI ATTN: HILLARD W WELCH 344 ANNABELLE POINT RD CENTERVILLE, MA 02632	510(k) NO: K994028 PHONE NO : 508-771-6777	DEVICE: FLIPO XENON CURING LIGHT SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
LONGBEST (XIAMEN) BALLS CO., LTD ATTN: CHIEN LIN NO. 18 CHIN LIU ST SHIAUKANG DIST. KAOHSIUNG,	510(k) NO: K993847 PHONE NO : 773-327-2054	DEVICE: TEH LOONG, VINYL, POWDERED, PATIENT EXAMINATION GLOVES SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
LONGBEST (XIAMEN) BALLS CO., LTD ATTN: CHIEN LIN NO. 18 CHIN LIU ST SHIAUKANG DIST. KAOHSIUNG,	510(k) NO: K993849 PHONE NO : 773-327-2054	DEVICE: TEH LOONG VINYL, POWDER-FREE, PATIENT EXAMINATION GLOVE SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
LPG USA, INC. BRATOR ATTN: JOCELYNE ROLLAND 3101 NORTH FEDERAL HWY. #301 FORT LAUDERDALE, FL 33306	510(k) NO: K990445 PHONE NO : 954-569-5005	DEVICE: LPG THERAPEUTIC MASSAGER, MODELS -ESI, THERAPEUTIC MASSAGER/VI SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MAGSTIM CORPORATION US ATTN: REZA JALINOUS 730 FIFTH AVE. 9TH FLOOR NEW YORK, NY 10019	510(k) NO: K992911 PHONE NO : 888-624-7846	DEVICE: MAGSTIM RAPID SE DECISION MADE: 07-JAN-2000 510(k) STATEMENT
MAJOR MOBILITY PRODUCTS, INC. ATTN: SCOTT SCHWEISS 18206 MANCE CT. HOUSTON, TX 77094	510(k) NO: K994185 PHONE NO : 281-398-9365	DEVICE: MANUAL WHEELCHAIR SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT
MDS ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD., SUITE 200 NEW YORK, NY 11021	510(k) NO: K992727 PHONE NO : 203-431-1511	DEVICE: THE BI-DIRECTIONAL SPIRAL & EPOXY ROOT CANAL CEMENT SYSTEM SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDI-MAN REHABILITATION PRODUCTS ATTN: JOHN T MOGENSEN 6200 TOMKEN ROAD MISSISSAUGA, ONTARIO,	510(k) NO: K992779 PHONE NO : 905 565 1480	DEVICE: A-2000 BATHING SYSTEMS; HYDROSONIC BATHING SYSTEM SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT

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MEDISON AMERICA, INC. ATTN: GARY J ALLESHROOK 6616 OWENS DR. PLEASANTON, CA 94588	510(k) NO: K000030 PHONE NO : 925-201-1954	DEVICE: SONOPACE 600 DIAGNOSTIC ULTRASOUND SYSTEM SE DECISION MADE: 19-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDISYSTEMS CORP. ATTN: LARRY R PILOT 1900 K STREET, N.W. WASHINGTON, DC 20006	510(k) NO: K990803 PHONE NO : 202-496-7500	DEVICE: MEDISYSTEMS BUTTONHOLE NEEDLE SETS SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDLOGIC GLOBAL CORP. ATTN: STEPHEN J TAMSETT 4815 LIST DR., SUITE 111 COLORADO SPRINGS, CO 80919	510(k) NO: K993556 PHONE NO : 800-625-6442	DEVICE: LIQUIBAND DENTAL SE DECISION MADE: 03-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC PERFUSION SYSTEMS ATTN: MARIE HOLM 7611 NORTHLAND DR. MINNEAPOLIS, MN 55428	510(k) NO: K994208 PHONE NO : 612-391-9000	DEVICE: AFFINITY 20 MICRON ARTERIAL BLOOD FILTER, MODEL 353/354 SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. TED RECORDER AND MODEL 6191 PATIENT ACTIVATOR ATTN: NORA K HADDING 4000 LEXINGTON AVE. N SHOREVIEW, MN 55126-2983	510(k) NO: K994331 PHONE NO : 612-514-9500	DEVICE: REVEAL PLUS INSERTABLE LOOP RECORDER SYSTEM, MODEL 9526 IMPLAN SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MEGA ELECTRONICS LTD. SYSTEM, MODEL FS-HMTR ATTN: DAVID MAHONEY 200 NORTH MAIN STREET SOUTH BUILDING, SUITE 6 EAST LONGMEADOW, MA 01028	510(k) NO: K993411 PHONE NO : 413-525-6313	DEVICE: FEMISCAN CLINIC SYSTEM, MODEL FS-ICTRA AND FEMISCAN PERSONAL S SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MERIT MEDICAL SYSTEMS, INC. ATTN: CHESTER MCCOY 1600 WEST MERIT PKWY. SOUTH JORDAN, UT 84095	510(k) NO: K994253 PHONE NO : 801-253-1600	DEVICE: VACLOK SYRINGE SE DECISION MADE: 05-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICK RADIO-NUCLEAR INSTRUMENTS, ATTN: FELIX MICK 1470 OUTLOOK AVE. BRONX, NY 10465	IN510(k) NO: K993400 PHONE NO : 718-597-3999	DEVICE: HDR CONTOUR TP TEMPLATE AND IMPLANT ACCESSORIES SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICK RADIO-NUCLEAR INSTRUMENTS, ATTN: FELIX MICK 1470 OUTLOOK AVE. BRONX, NY 10465	IN510(k) NO: K993472 PHONE NO : 718-597-3999	DEVICE: SEGMENTED VAGINAL APPLICATOR SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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MICOMED GMBH ATTN: CHARMAINE HENDERSON 511 CATALINA ROAD FULLERTON, CA 92835	510(k) NO: K991862 PHONE NO : 714-525-8441	DEVICE: MICOMED POSTERIOR DOUBLEROD SYSTEM (MPDS) SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICRO DETECT, INC. ATTN: MEHDI ALEM 2852 WALNUT AVE. TUSTIN, CA 92780	510(k) NO: K993635 PHONE NO : 714-832-8234	DEVICE: MDI SM/RNP TEST SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICRO DETECT, INC. ATTN: MEHDI ALEM 2852 WALNUT AVE. TUSTIN, CA 92780	510(k) NO: K993636 PHONE NO : 714-832-8234	DEVICE: MDI SS-A TEST SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICRO DETECT, INC. ATTN: MEHDI ALEM 2852 WALNUT AVE. TUSTIN, CA 92780	510(k) NO: K993843 PHONE NO : 714-832-8234	DEVICE: MDI RF TEST SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICRO DETECT, INC. BODIES TO SS-B IN HUMAN SERUM ATTN: MEHDI ALEM 2852 WALNUT AVE. TUSTIN, CA 92780	510(k) NO: K993971 PHONE NO : 714-832-8234	DEVICE: MDI SS-B TEST ENZYME IMMUNOASSAY FOR THE DETECTION OF AUTOANTI SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICRO DETECT, INC. ATTN: MEHDI ALEM 2852 WALNUT AVE. TUSTIN, CA 92780	510(k) NO: K994029 PHONE NO : 714-832-8234	DEVICE: MDI SM TEST SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MICRO THERAPEUTICS, INC. ATTN: TOM DAUGHTERS 2 GOODYEAR IRVINE, CA 92618	510(k) NO: K993672 PHONE NO : 949-837-3700	DEVICE: REBAR MICRO CATHETER, MODELS 105-5080, 105-5086 SE DECISION MADE: 04-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MIDMARK CORP. ATTN: MIKE SNYDER 60 VISTA DR. P.O. BOX 286 VERSAILLES, OH 45380	510(k) NO: K992744 PHONE NO : 937-526-8390	DEVICE: MIDMARK M4*9 EASYCLAVE STEAM STERILIZER SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MILLENNIUM MEDICAL DISTRIBUTION, ATTN: CHRISTINE EMANUEL 1205 DE LA VINA SANTA BARBARA, CA 93101	510(k) NO: K993848 PHONE NO : 805-963-4312	DEVICE: MILLENNIUM HUBER PLUS SAFETY INFUSION SET SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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MINIMED TECHNOLOGIES, INC. ATTN: JENNIFER LYONS 12744 SAN FERNANDO RD. SYLMAR, CA 91342	510(k) NO: K991936 PHONE NO : 818-362-5958	DEVICE: 3.0 ML RESERVOIR, MODEL 103/193 SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
MITSUI TEXTILE CORP. ATTN: WILLIAM J BARONE 1450 BROADWAY 22ND FLOOR NEW YORK, NY 10018	510(k) NO: K992604 PHONE NO : 212-827-1034	DEVICE: HENRY SCHEIN SURGICAL MASK SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT
MOTION CONCEPTS ATTN: ALLEN BOYD 101 BARTLEY DRIVE TORONTO, ONTARIO,	510(k) NO: K994241 PHONE NO : 416 759 9937	DEVICE: TRX-CG POWER TILT AND RECLINE SYSTEM SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT
MTP MEDICAL TECHNICAL PROMOTION ATTN: KEVIN KENNAN P.O. BOX 1954 CULVER CITY, CA 90232	510(k) NO: K994066 PHONE NO : 310-410-2769	DEVICE: MTP DISPOSABLE TROCARS SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
NANMA MFG CO., LTD. ATTN: E.J. SMITH P.O. BOX 4341 CROFTON, MD 21114	510(k) NO: K993906 PHONE NO : 410-451-0639	DEVICE: NANMA NON-ADJUSTABLE CONSTRICTION RING SE DECISION MADE: 31-JAN-2000 510(k) STATEMENT
NANMA MFG CO., LTD. ATTN: E.J. SMITH P.O. BOX 4341 CROFTON, MD 21114	510(k) NO: K993908 PHONE NO : 410-451-0639	DEVICE: NANMA AJUSTABLE CONSTRICTION RING SE DECISION MADE: 31-JAN-2000 510(k) STATEMENT
NEUROCYBERNETICS ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD SUITE 200 GREAT NECK, NY 11021	510(k) NO: K993654 PHONE NO : 203-431-1511	DEVICE: NEUROCOMP SE DECISION MADE: 27-JAN-2000 510(k) STATEMENT
NEW STAR LASERS, INC. ATTN: DONALD V JOHNSON 11802 KEMPER RD. AUBURN, CA 95603	510(k) NO: K994273 PHONE NO : 530-823-1434	DEVICE: MODEL 1000 HOLMIUM LASER SYSTEM SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
NHE CORPORATION ATTN: SHUGEN ZHANG 7100 FERNWOOD AVE SUITE 1922 RICHMOND, VA 23228	510(k) NO: K992584 PHONE NO : 804-755-1633	DEVICE: PE 501 PC-ECG MONITOR SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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NIHON KOHDEN AMERICA, INC. ATTN: BONNIE BISHOP 2601 CAMPUS DR. IRVINE, CA 92612-1601	510(k) NO: K992455 PHONE NO : 949-250-3959	DEVICE: NIHON KOHDEN OGS-2001A POCKETCARE AND ACCESSORIES SE DECISION MADE: 07-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
NIPRO MEDICAL CORP. ATTN: KAELYN HADLEY 1384 COPPERFIELD COURT LEXINGTON, KY 40514-1268	510(k) NO: K992729 PHONE NO : 606-224-8256	DEVICE: NIPRO LUER ADAPTOR SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
NOBEL BIOCARE USA, INC. TE LOADING UPON PLACEMENT) ATTN: JEFF HAUSHEER 22725 SAVI RANCH PKWY. YORBA LINDA, CA 92887	510(k) NO: K993595 PHONE NO : 714-282-4800	DEVICE: NOBEL BIOCARE'S MODIFIED SURFACE IMPLANT (INTENDED FOR IMMEDIA SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
NORTHGATE TECHNOLOGIES, INC. ATTN: CASEY KUREK 600 CHURCH RD. ELGIN, IL 60123	510(k) NO: K993778 PHONE NO : 847-608-8900	DEVICE: HYDROTOWER MANAGEMENT SYSTEM, MODEL 4-750-00 SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
NUCLETRON CORP. ATTN: RALPH E SHUPING 7080 COLUMBIA GATEWAY DR. COLUMBIA, MD 21046-2133	510(k) NO: K992434 PHONE NO : 410-312-4100	DEVICE: ITP, MODEL 1.0 SE DECISION MADE: 13-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
OHMEDA MEDICAL ATTN: ALBERTO F PROFUMO 9065 GUILFORD RD. COLUMBIA, MD 21046-1801	510(k) NO: K993407 PHONE NO : 410-381-4004	DEVICE: OHMEDA MEDICAL OMNIBED SE DECISION MADE: 05-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
OLYMPUS DIAGNOSTICA GMBH ATTN: LAURA STORMS-TYLER TWO CORPORATE CENTER DRIVE MELVILLE, NY 11747	510(k) NO: K994189 PHONE NO : 516-844-5688	DEVICE: OLYMPUS CREATINE KINASE REAGENT OSR6179/6279 SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
OMNIGRACE LTD. MER COATED ATTN: WILLIAM E PATTON 7815 VANDERBILT DRIVE NW NORTH CANTON, OH 44720	510(k) NO: K994246 PHONE NO : 330-966-8878	DEVICE: OMNI GRACE NITRILE, BLUE, EXAMINATION GLOVE, POWDER-FREE, POLY SE DECISION MADE: 31-JAN-2000 510(k) STATEMENT
ORATEC INTERVENTIONS, INC. ATTN: SHEILA RAMERMAN 3700 HAVEN CT. MENLO PARK, CA 94025	510(k) NO: K994333 PHONE NO : 650-369-9904	DEVICE: ORA-50 ELECTROTHERMAL SYSTEM AND ACCESSORIES SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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PACIFIC SURGICAL INNOVATIONS, INC. ATTN: TERRY JOHNSTON 360 INDUSTRIAL RD., UNIT H SAN CARLOS, CA 94070	510(k) NO: K991959 PHONE NO : 650-802-6988	DEVICE: PSI TITANIUM ANEURYSM CLIP SE DECISION MADE: 06-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
PAULINE M. NICHOLLS ATTN: PAULINE M NICHOLLS 321 SOUTH BROAD STREET MONROE, GA 30655	510(k) NO: K971732 PHONE NO : 770-267-7963	DEVICE: DENTAL HANDPIECE SE DECISION MADE: 11-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
PHARMACIA & UPJOHN CO. ATTN: KAREN E MATTIS 5094 ST. ANDREWS DRIVE WESTERVILLE, OH 43082	510(k) NO: K993585 PHONE NO : 614-794-3324	DEVICE: VARELISA TPO ANTIBODIES, MODEL 12348/12396 SE DECISION MADE: 05-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
POLYMER TECHNOLOGY SYSTEMS, INC. ATTN: MARGO ENRIGHT 7736 ZIONSVILLE RD. INDIANAPOLIS, IN 46268	510(k) NO: K993377 PHONE NO :	DEVICE: MIM BIOSCANNER HDL TEST STRIPS, OVER THE COUNTER (OTC) SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT
PRECISION DYNAMICS CORP. ATTN: KALYNA SNYLYK 13880 DEL SUR ST. SAN FERNANDO, CA 91340-3490	510(k) NO: K994263 PHONE NO : 818-897-1111	DEVICE: SECURLINE UMBILICAL CORD CLAMP CLIPPER #3540 SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
PRIME DENTAL MANUFACTURING, INC. ATTN: ROLANDO MARASIGAN 3735 WEST BELMONT AVE. CHICAGO, IL 60618	510(k) NO: K994224 PHONE NO : 773-539-5927	DEVICE: PRIME-DENT CHEMICAL CURE COMPOSITE RESTORATIVE MATERIAL SE DECISION MADE: 31-JAN-2000 510(k) STATEMENT
PROCTER & GAMBLE CO. ATTN: MARK M ANDERSON 6100 CENTER HILL AVE. CINCINNATI, OH 45224	510(k) NO: K993870 PHONE NO : 513-634-5196	DEVICE: UNSENTED INTERLABIAL MENSTRUAL PAD SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
PROMEX, INC. ATTN: JOSEPH L MARK 3049 HUDSON STREET FRANKLIN, IN 46131	510(k) NO: K994272 PHONE NO : 317-736-0128	DEVICE: AUTOMATED CORE BIOPSY DEVICE SE DECISION MADE: 07-JAN-2000 510(k) STATEMENT
PURE WATER, INC. ATTN: CYNTHIA P WALTERS 305 WEST MARKET STREET ANDERSON, SC 29624	510(k) NO: K992786 PHONE NO : 864-375-0105	DEVICE: PURE WATER, INC.'S WATER PURIFICATION SYSTEMS SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
PURE WATER, INC. H OPTIONAL REMOTE FILL ATTN: RHONDA S MCCOY 305 WEST MARKET STREET ANDERSON, SC 29624	510(k) NO: K993058 PHONE NO : 864-375-0105	DEVICE: PURE WATER INC'S ACIDIFIED STORAGE AND DISTRIBUTION SYSTEM WIT SE DECISION MADE: 24-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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RADIOMETER AMERICA, INC. ATTN: VINCENT M SIGMUND 810 SHARON DR. WESTLAKE, OH 44145-1598	510(k) NO: K992859 PHONE NO : 440-871-8900	DEVICE: ABL700 SERIES ANALYZER WITH AUTOCHECK MODULE SE DECISION MADE: 10-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
RHEALM PHARMACEUTICALS, INC. ATTN: RICHARD MANN 258 SE 6TH AVE., SUITE 12 DELRAY BEACH, FL 33483	510(k) NO: K992286 PHONE NO : 561-736-1880	DEVICE: DERMAFREEZE SE DECISION MADE: 21-JAN-2000 510(k) STATEMENT
RHIGENE, INC ATTN: DAVE KOLESAR 455 STATE ST., SUITE 104 DES PLAINES, IL 60068	510(k) NO: K994071 PHONE NO : 847-375-9091	DEVICE: RHIGENE ANA ELISA TEST SYSTEM SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
ROCHE DIAGNOSTICS CORP. COAGUCHEK PRO SYSTEM ATTN: LUANN OCHS 9115 HAGUE RD. INDIANAPOLIS, IN 46250-0457	510(k) NO: K992851 PHONE NO : 317-845-2000	DEVICE: ACT TEST CATRIDGES FOR COAGUCHEK PRO SYSTEM, ACT CONTROLS FOR SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ROCHE DIAGNOSTICS CORP. ATTN: JENNIFER TRIBBETT 9115 HAGUE RD. INDIANAPOLIS, IN 46250-0457	510(k) NO: K994017 PHONE NO : 317-576-3742	DEVICE: ONTRAK TESTCUP 5 M2K, CAT. 11 1850 1 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ROCHE DIAGNOSTICS CORP. ATTN: JENNIFER TRIBBETT 9115 HAGUE RD. INDIANAPOLIS, IN 46250-0457	510(k) NO: K994020 PHONE NO : 317-576-3742	DEVICE: ONTRAK TESTSTIK FOR PCP, CAT. 07 6654 2 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ROCHE DIAGNOSTICS CORP. ATTN: JENNIFER TRIBBETT 9115 HAGUE RD. INDIANAPOLIS, IN 46250-0457	510(k) NO: K994030 PHONE NO : 317-576-3742	DEVICE: ONTRAK TESTCUP 5, CAT. 07 6481 7 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
ROSSMAX INTL. LTD. 4 ATTN: MICHAEL YEH 2F. NO. 8, ALLEY 20 LANE 106 SECTION 3, NAN KANG ROAD TAIPEI,	510(k) NO: K993426 PHONE NO : 011 886 27835584	DEVICE: ROSSMAX AUTOMATIC WRISTWATCH BLOOD PRESSURE MONITOR, MODEL Z4 SE DECISION MADE: 07-JAN-2000 510(k) STATEMENT
ROSSMAX INTL. LTD. ATTN: MICHAEL YEH 2F. NO. 8, ALLEY 20 LANE 106 SECTION 3, NAN KANG ROAD TAIPEI,	510(k) NO: K993429 PHONE NO : 011 886 27835584	DEVICE: ROSSMAX AUTOMATIC WRISTWATCH BLOOD PRESSURE MONITOR, MODEL Z40 SE DECISION MADE: 07-JAN-2000 510(k) STATEMENT

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ROSSMAX INTL. LTD. ATTN: MICHAEL YEH 2F. NO. 8, ALLEY 20 LANE 106 SECTION 3, NAN KANG ROAD TAIPEI,	510(k) NO: K993460 PHONE NO : 011 886 2783	DEVICE: ROSSMAX AUTOMATIC WRISTWATCH BLOOD PRESSURE MONITOR, MODEL Z43 SE DECISION MADE: 11-JAN-2000 510(k) STATEMENT
ROTEC MEDIZINTECHNIK GMBH ATTN: ING ULRICH HOLZWARTH AM MUHLBERG 31 WEISENDORF,	510(k) NO: K992403 PHONE NO : 499 135 3215	DEVICE: MRP-TITAN SE DECISION MADE: 21-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SAFESKIN CORP. ATTN: EUGENE V GOORCHENKO 12671 HIGH BLUFF DR. SAN DIEGO, CA 92130	510(k) NO: K994081 PHONE NO : 858-509-7010	DEVICE: SAFESKIN TACTYLON PF POWDER-FREE SURGEON'S GLOVES SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SAGE BIOPHARMA FREEZING MEDIUM, 9% GLYCEROL, 0.2 M SUCROSE FREEZING MEDI ATTN: GREG HOLLAND 3722 AVE. SAUSALITO IRVINE, CA 92606	510(k) NO: K991390 PHONE NO : 949-262-0411	DEVICE: 1.5 M PROPANEDIOL FREEZING MEDIUM, 1.5 PROPANEDIOL 0.1 SUCROSE SE DECISION MADE: 18-JAN-2000 510(k) STATEMENT
SALTER LABS ATTN: DUANE KAZAL 100 W. SYCAMORE ROAD ARVIN, CA 93203	510(k) NO: K992285 PHONE NO : 805-854-3166	DEVICE: SALTER AIRE COMPRESSOR SE DECISION MADE: 07-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SDI DIAGNOSTICS, INC. ATTN: MICHAEL J BOYLE 10 HAMPDEN DR. EASTON, MA 02375	510(k) NO: K990962 PHONE NO : 508-238-7033	DEVICE: FLOSENSE, MODEL 29-8010 SE DECISION MADE: 07-JAN-2000 510(k) STATEMENT
SHANGHAI GLOVMAX ENTERPRISE CO.,LT NT EXAMINATION GLOVES ATTN: MAO-SHENG LEE NANKING E. RD., SEC 3 TAIPEI,	510(k) NO: K993859 PHONE NO : 886 225 462479	DEVICE: SHANGHAI GLOVMAX ENTERPRISE CO., LTD. PRE-POWDERED VINYL PATIE SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SHANGHAI GLOVMAX ENTERPRISE CO.,LT T EXAMINATION GLOVES ATTN: MAO-SHENG LEE NANKING E. RD., SEC 3 TAIPEI,	510(k) NO: K993880 PHONE NO : 886 227 136677ET2	DEVICE: SHANGHAI GLOVMAX ENTERPRISE CO, LTD., POWDER-FREE VINYL PATIEN SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SHINEMOUND ENTERPRISE, INC. MINATION GLOVES WITH BEIGE PIGMENT ADDITIVES ATTN: HUAN-CHUNG LI 17A STERLING RD. NORTH BILLERICA, MA 01862	510(k) NO: K994248 PHONE NO : 978-436-9980	DEVICE: SENSI-PRO, DISPOSABLE PRE-POWDERED SYNTHETIC VINYL PATIENT EXA SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT

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SHINEMOUND ENTERPRISE, INC. NATION GLOVES WITH BEIGE PIGMENT ADDITIVES ATTN: HUAN-CHUNG LI 17A STERLING RD. NORTH BILLERICA, MA 01862	510(k) NO: K994258 PHONE NO : 978-436-9980	DEVICE: SENSI-PRO DISPOSABLE POWDER FREE SYNTHETIC VINYL PATIENT EXAMI SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
SIEMENS MEDICAL CORP. ATTN: JAMIE YIEH 186 WOOD AVE. SO. ISELIN, NJ 08830	510(k) NO: K994316 PHONE NO : 732-321-4625	DEVICE: MAGNETOM OPEN VIVA WITH PERMANENT MAGNET SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SYSTEMS, INC. ATTN: PENELOPE H GRECCO 16 ELECTRONICS AVE. DANVERS, MA 01923	510(k) NO: K992116 PHONE NO : 978-907-7500	DEVICE: SIEMEMNS INFINITY ETCO2 POD SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIGMA DISTRIBUTION & SUPPLY, INC. ATTN: ARTHUR KESHISHYAN 701 WEST HARVARD STREET GLENDALE, CA 91204	510(k) NO: K993963 PHONE NO : 818-246-4624	DEVICE: SIGMA MANUAL WHEELCHAIR SE DECISION MADE: 13-JAN-2000 510(k) STATEMENT
SIMS DELTEC, INC. ATTN: LISA STONE 1265 GREY FOX RD. ST. PAUL, MN 55112	510(k) NO: K994216 PHONE NO : 651-628-7224	DEVICE: PLASTIC PORT IMPLANTABLE VENOUS ACCESS SYSTEM SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SIMS PORTEX, INC. PONSE PEDIATRIC MANUAL RESUSCITATOR, BAG RESERVOIR, 1ST RE ATTN: TIMOTHY J TALCOTT 10 BOWMAN DR. KEENE, NH 03431	510(k) NO: K991861 PHONE NO : 603-352-3812	DEVICE: 1ST RESPONSE INFANT MANUAL RESUSCITATOR, BAG RESEVOIR, 1ST RES SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW ENDOSCOPY, INC. ATTN: DEMETRIOS TSAKONAS 130 FORBES BOULEVARD MANSFIELD, MA 02048	510(k) NO: K992396 PHONE NO : 508-261-3775	DEVICE: BIORCI SCREW SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW, INC. ATTN: DAVID HENLEY 1450 E. BROOKS ROAD MEMPHIS, TN 38116	510(k) NO: K991162 PHONE NO : 901-396-2121	DEVICE: BICLOX ALUMINA CERAMIC FEMORAL HEAD SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SMITH & NEPHEW, INC. ATTN: JANICE HASELTON 160 DASCUMB RD. ANDOVER, MA 01810	510(k) NO: K994084 PHONE NO : 978-749-1494	DEVICE: SMITH & NEPHEW XENON LIGHT SOURCES AND ACCESSORIES SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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SPACELABS MEDICAL, INC. ATTN: NANCY GERILAR 15220 NORTH EAST 40TH ST. REDMOND, WA 98052	510(k) NO: K992749 PHONE NO : 425-867-7315	DEVICE: ULTRAVIEW WAVEFORM PAGER SYSTEM, MODEL 91841 SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
STARION INSTRUMENTS ATTN: BRIAN GRIGSEY 20665 4TH ST. SARATOGA, CA 95070	510(k) NO: K994019 PHONE NO : 408-741-8773	DEVICE: CAUTERY GRASPER/DISSECTOR SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
STELLARTECH RESEARCH CORP. ECH RADIOFREQUENCY GENERATOR, MODEL 1025A-230 ATTN: JAMES R SANTOS 1346 BORDEAUX DR. SUNNYVALE, CA 94089	510(k) NO: K994173 PHONE NO : 408-331-3000	DEVICE: STELLARTECH RADIOFREQUENCY GENERATOR, MODEL 1025A-115, STELLARI SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
STRECK LABORATORIES, INC. ATTN: PAUL KITTELSON 14124 INDUSTRIAL RD. OMAHA, NE 68145-0625	510(k) NO: K994388 PHONE NO : 402-691-7465	DEVICE: XE CHECK SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
STRYKER CORP. ATTN: NICOLE PETTY 4100 EAST MILHAM AVENUE KALAMAZOO, MI 49001-6197	510(k) NO: K993239 PHONE NO : 616-323-7700	DEVICE: STRYKER NAVIGATION SYSTEM - NEURO MODULE, MODEL 6000-XXX-XXX SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SULZER MEDICA ATTN: EDWARD E NEWTON 1300 EAST ANDERSON LANE AUSTIN, TX 78752-1793	510(k) NO: K993667 PHONE NO : 512-435-3407	DEVICE: SULZER VASCUTEK SEALPTFE VASCULAR PROSTHESIS SE DECISION MADE: 28-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SUPERMAX SDN BHD ATTN: STANLEY THAI LOT 42, PUTRA INDUSTRIAL PARK BUKIT RAHMAN PUTRA 47000 SUNGAI BULOH SELANGOR,	510(k) NO: K993864 PHONE NO : 603 657 2328	DEVICE: COLORED AND FLAVORED POWDER FREE LATEX EXAMINATION GLOVES SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
SUPERMAX SDN BHD ATTN: STANLEY THAI LOT 42, PUTRA INDUSTRIAL PARK BUKIT RAHMAN PUTRA 47000 SUNGAI BULOH SELANGOR,	510(k) NO: K993865 PHONE NO : 603 657 2328	DEVICE: GREEN PEPPERMINT FLAVORED POWDERED LATEX EXAMINATION GLOVES SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
SURGICAL IMPLANTS, INC. ATTN: DOUGLAS W STUART 962 SOUTH TAMiami TRAIL, #203 SARASOTA, FL 34326	510(k) NO: K993713 PHONE NO : 941-366-1882	DEVICE: RIM-FTX, ACETABULAR CUP SE DECISION MADE: 28-JAN-2000 510(k) STATEMENT

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SYNOCR PHARMACEUTICALS, INC. ATTN: GARY GILMORE 1313 WASHINGTON AVENUE GOLDEN, CO 80401	510(k) NO: K992007 PHONE NO : 303-279-1014	DEVICE: PHARMASEED, MODEL BT-103-1 SE DECISION MADE: 14-JAN-2000 510(k) STATEMENT
SYVA CO. D 6E91-01 ATTN: PAUL L ROGERS JR. 3403 YERBA BUENA RD. SAN JOSE, CA 95161-9013	510(k) NO: K993026 PHONE NO : 408-239-2309	DEVICE: ABBOTT AEROSET PHENYTOIN ASSAY AND CALIBRATORS; MODELS 1E07 AN SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. 2 AND 6E90 ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. SAN JOSE, CA 95161-9013	510(k) NO: K993028 PHONE NO : 408-239-2309	DEVICE: ABBOTT AEROSET CARBAMAZEPINE ASSAY AND CALIBRATORS; MODELS 1E1 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. AND 6E89 ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. SAN JOSE, CA 95161-9013	510(k) NO: K993029 PHONE NO : 408-239-2309	DEVICE: ABBOTT AEROSET THEOPHYLLINE ASSAY AND CALIBRATORS; MODELS 1E09 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. AND 5F54 ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. SAN JOSE, CA 95161-9013	510(k) NO: K993031 PHONE NO : 408-239-2309	DEVICE: ABBOTT AEROSET PHENOBARBITAL ASSEY AND CALIBRATORS;MODELS 1E08 SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. 129UL ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993982 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS AMPHETAMINE/METHAMPHETAMINE ASSAY 9C029UL/9C SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993983 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS PHENCYCLIDINE ASSAY, MODEL 9J029UL SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993984 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS CANNABINOID ASSAY, MODELS 9N029UL/9N129UL SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993985 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS BENZODIAZEPINE ASSAY, MODELS 9F029UL/9F129UL SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993986 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS METHAQUALONE ASSAY, MODEL 9Q029UL/9Q129UL SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993987 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS BARBITURATE ASSAY, MODEL 9D029UL/9D129UL SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K993988 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS COCAINE METABOLITE ASSAY, MODEL 9H029UL SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
SYVA CO. ATTN: PAUL L ROGERS 3403 YERBA BUENA RD. P.O. BOX 49013 SAN JOSE, CA 95161-9013	510(k) NO: K994005 PHONE NO : 408-239-2309	DEVICE: SYVA EMIT II PLUS METHADONE ASSAY, MODELS 9E029UL/9E129UL SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
TECHSTYLES, INC. ATTN: STEPHANIE T HOWARD 16415 ADDISON RD., SUITE 850 ADDISON, TX 75001	510(k) NO: K992436 PHONE NO : 972-732-7694	DEVICE: GOWN BACK, MODEL 13-403N; 13-404N; 13-405N SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
TECO DIAGNOSTICS ND A504-500H ATTN: DINDO CARRILLO 4925 EAST HUNTER AVE. ANAHEIM, CA 92807	510(k) NO: K000067 PHONE NO : 714-693-7788	DEVICE: ALKALINE PHOSPHATASE LIQUID REAGENT-KINETIC, MODELS A504-150 A SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
TFX MEDICAL GROUP ATTN: JULIE A BEALMONT TALL PINES PARK JAFFREY, NH 03452	510(k) NO: K991647 PHONE NO : 603-532-7706	DEVICE: TFX MEDICAL INTRODUCER KIT SE DECISION MADE: 04-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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THAI NIPPON RUBBER INDUSTRY CO., ATTN: ELI J CARTER 1219 LITTLE CREEK RD. DURHAM, NC 27713	510(k) NO: K994095 PHONE NO : 919-544-7040	DEVICE: LATEX CONDOM SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
THE KENDALL COMPANY, L.P. ATTN: DAVID A OLSON 15 HAMPSHIRE ST. MANSFIELD, MA 02048	510(k) NO: K990530 PHONE NO : 508-261-8530	DEVICE: KERLIX MD ANTIMICROBIAL GAUZE DRESSING SE DECISION MADE: 31-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
THERASENSE, INC. ATTN: EVE A CONNER 1360 SOUTH LOOP DRIVE ALAMEDA, CA 94502	510(k) NO: K992684 PHONE NO : 510-749-5400	DEVICE: FREESTYLE BLOOD GLUCOSE MONITORING SYSTEM SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
TOP GLOVE SDN. BHD. ATTN: WEE-CHAI LIM LOT 4968 JALAN TERATAI, BATU 6 OFFJALAN MERU, 41050 KLANG SELANGOR, D.E.,	510(k) NO: K993664 PHONE NO : 603 392 19921905	DEVICE: SYNTHETIC VINYL MEDICAL EXAMINATION POWDERED GLOVES SE DECISION MADE: 11-JAN-2000 510(k) STATEMENT
TOSHIBA AMERICA MRI, INC. ATTN: KEN NEHMER 280 UTAH AVE. SOUTH SAN FRANCISCO, CA 94080-6883	510(k) NO: K993574 PHONE NO : 650-872-2722	DEVICE: OPART/PRODIGA, OPART/PROTENZA, OPART/PARAGON SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
TRINITY BIOTECH USA ATTN: WAYNE KVEIKOSKY 2823 GIRTS RD. JAMESTOWN, NY 14702	510(k) NO: K993839 PHONE NO : 716-483-3851	DEVICE: ENA PROFILE ELISA TEST SYSTEM SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
UNICARE BIOMEDICAL ATTN: STAN YANG 25951 LA CUESTA AVENUE LAGUNA HILLS, CA 92653	510(k) NO: K993784 PHONE NO : 949-362-1772	DEVICE: UNIGRAFT SE DECISION MADE: 27-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
USA INSTRUMENTS, INC. ATTN: RONY THOMAS 1515 DANNER DRIVE AURORA, OH 44202	510(k) NO: K994040 PHONE NO : 330-562-1000	DEVICE: PHASED ARRAY KNEE AND FOOT COIL SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
USA INSTRUMENTS, INC. ATTN: RONY THOMAS 1515 DANNER DRIVE AURORA, OH 44202	510(k) NO: K994042 PHONE NO : 330-562-1000	DEVICE: SHARP 9000 PHASED ARRAY BRAIN COIL SE DECISION MADE: 31-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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VASCUTECH, INC. ATTN: TRENT G KAMKE 164 MIDDLESEX TURNPIKE BURLINGTON, MA 01803	510(k) NO: K992941 PHONE NO : 781-221-2266	DEVICE: LEMAITRE BILIARY CATHETER SE DECISION MADE: 12-JAN-2000 510(k) STATEMENT
VIDAR SYSTEMS CORP. TION, MODEL 13205 ATTN: MARY "PENNIE" DRINKARD 460 SPRING PARK PL. HERNDON, VA 20170	510(k) NO: K993598 PHONE NO : 703-471-7070	DEVICE: MAMMOGRAPHY PRO, MODEL 13017, DIAGNOSTIC PRO W/ MAMMOGRAPHY OF SE DECISION MADE: 20-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
VIDAR SYSTEMS CORP. EIRY PRO, MODEL 13019 ATTN: MARY "PENNIE" DRINKARD 460 SPRING PARK PL. HERNDON, VA 20170	510(k) NO: K993599 PHONE NO : 703-471-7070	DEVICE: DIAGNOSTIC PRO, MODEL 12772, VXR-16, MODEL 13020, VXR-16 DOSIM SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
VIRGINIA WATER SYSTEMS, INC. YSIS ATTN: WILLIAM G GARRAHAN 7433 WHITEPINE RD. RICHMOND, VA 23237	510(k) NO: K991916 PHONE NO : 804-743-0034	DEVICE: VIRGINIA WATER SYSTEMS' WATER PURIFICATION SYSTEM FOR HEMODIAL SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
VOCO GMBH ATTN: SHUOJIA DONG 4235 BEACONSFIELD MONTREAL,	510(k) NO: K993827 PHONE NO : 450 646 1330	DEVICE: UFI GEL HARD SE DECISION MADE: 20-JAN-2000 510(k) STATEMENT
VOCO GMBH ATTN: EVAN DICK 7527 WESTMORELAND AVE. ST. LOUIS, MO 63105	510(k) NO: K994056 PHONE NO : 314-721-0112	DEVICE: ADMIRA SE DECISION MADE: 12-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
WAKO CHEMICALS, USA, INC. TANDARD ATTN: TONYA MALLORY 1600 BELLWOOD RD. RICHMOND, VA 23237	510(k) NO: K993924 PHONE NO : 800-992-9256	DEVICE: WAKO IGM II- HA, IMMUNOLOBULIN CALIBRATOR SET, IMMUNOLOBULIN S SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
WAKO CHEMICALS, USA, INC. STANDARD ATTN: TONYA MALLORY 1600 BELLWOOD RD. RICHMOND, VA 23237	510(k) NO: K993927 PHONE NO : 800-992-9256	DEVICE: WAKO IGA II-HA, IMMUNOGLOBULIN CALIBRATOR SET, IMMUNOGLOBULIN SE DECISION MADE: 14-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA
WAKO CHEMICALS, USA, INC. TANDARD ATTN: TANYA MALLORY 1600 BELLWOOD RD. RICHMOND, VA 23237	510(k) NO: K993928 PHONE NO : 800-992-9256	DEVICE: WAKO-IGG II-HA, IMMUNOGLOBULIN CALIBRATOR SET, IMMUNOLOBULIN S SE DECISION MADE: 18-JAN-2000 510(k) SUMMARY AVAILABLE FROM FDA

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WEAR SAFE MALAYSIA SDN. BHD.
ATTN: CLAUDE COTTET
LOT 1, LEEBOH HISHAMUDDIN SATU,
NORTH KLANG STRAITS IND. AREA
PORT KLANG, SELANGOR, D.E.,

510(k) NO: K992675
PHONE NO : 03 376 3525

DEVICE: PATIENT NITRILE EXAMINATION GLOVES (POWDERED)
SE DECISION MADE: 20-JAN-2000

510(k) STATEMENT

WYNIEK DIAGNOSTICS, INC.
ATTN: SHU-CHING CHENG
6146 NANCY RIDGE DR.,
SUITE 101
SAN DIEGO, CA 92121

510(k) NO: K992658
PHONE NO : 858-452-3198

DEVICE: OSOM ULTRA STREP A TEST, MODEL 147
SE DECISION MADE: 18-JAN-2000

510(k) STATEMENT

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

510(k) NO: K992855
PHONE NO : 904-279-7532

DEVICE: XPS STRAIGHTSHOT OR MODEL 2000 MICRODEBRIDER SYSTEM OR XPS POW
SE DECISION MADE: 21-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

XOMED, INC.
ATTN: ROY BERENS
6743 SOUTHPOINT DR. NORTH
JACKSONVILLE, FL 32216

510(k) NO: K993582
PHONE NO : 904-296-6454

DEVICE: MODIFICATION TO LASER-SHIELD II
SE DECISION MADE: 20-JAN-2000
510(k) SUMMARY AVAILABLE FROM FDA

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

07-FEB-2000
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TOTAL 510(k)s THIS PERIOD	283
TOTAL WITH SUMMARIES	201
TOTAL WITH STATEMENTS	82