3D LINE USA, INC.
ATTN: KAREN H RIGAMONTI
2807 OLD COURT ROAD
BALTIMORE, MD 21208

510(k) NO: K011255
PHONE NO : 410-580-1730

DEVICE: 3D LINE STEROTACTIC HARDWARE ACCESSORIES
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013538
PHONE NO : 972-518-7864

DEVICE: ETHANOL
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ACKARD LABORATORIES
ATTN: RICHARD HETTENBACH
70 JACKSON DR.
P.O. BOX 1085
CRANFORD, NJ 07016

510(k) NO: K013972
PHONE NO : 908-276-6290

DEVICE: H/S ELLIPTOSPHERE CATHETER SET, MODEL 61-4005
SE DECISION MADE: 17-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013380

PHONE NO : 858-535-2030

DEVICE: ACON MOP ONE STEP OPIATE TEST STRIP, ACON MOP STEP OPIATE TEST

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

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

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

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

ALLEGIANCE HEALTHCARE CORP.
ESTED FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM
ATTN: ERICA SEIHI
1500 WAUKEGAN RD. BLDG. WM
MCGAW PARK, IL 60085

510(k) NO: K013302
PHONE NO : 847-785-3337

DEVICE: DURAPRENE STERILE SYNTHETIC POWDER-FREE SURGICAL GLOVES WITH T

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

ALLIANCE MEDICAL CORP.
ATTN: DON SELVEY
10232 SOUTH 51ST ST.
PHOENIX, AZ 85044

510(k) NO: K012631
PHONE NO : 480-763-5300

DEVICE: REPROCESSED SOFT TISSUE ABLATORS
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

APEX MEDICAL CORP.
ATTN: ALAN CHANGE
10TH FL., NO. 31, LANE 169,
KANG NING ST.
HSI CHIH CHEN, TAIPEI HSIEN,

510(k) NO: K013813
PHONE NO : 886 226 954170

DEVICE: MODIFICATION TO:APEX MEDICAL IF-4100
SE DECISION MADE: 14-DEC-2001

510(k) STATEMENT

APOLLO CORP.
ATTN: ADRIAN SWEEN
450 MAIN ST.
SOMERSET, WI 54025

510(k) NO: K012029
PHONE NO : 715-247-5625

DEVICE: REMEDY MODEL 2Z12
SE DECISION MADE: 31-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

945-0120

LST109

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

ARC MEDICAL, INC.
ATTN: HAL NORRIS
322 PATTERSON AVE.
SCOTTDALE, GA 30079
510(k) NO: K011212
PHONE NO : 800-950-2720
DEVICE: FILTERFLO H
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ARISTA LATINDO INDUSTRIAL, LTD. P.
ATTN: LINGA SUMARTA
128 JALAN KYAI HAJI MUHAMMAD
MANSYUR
JAKARTA BARAT,
510(k) NO: K013320
PHONE NO : 622 166 20201195
DEVICE: BLUE LATEX EXAMINATION GLOVES, POWDER FREE
SE DECISION MADE: 19-DEC-2001
510(k) STATEMENT

ATLANTECH MEDICAL DEVICES LTD.
ATTN: NICK WOODS
38 FREEMANS WAY
HARROGATE, NORTH YORKSHIRE,
510(k) NO: K013334
PHONE NO : 44 142 3888806
DEVICE: ENDOFLIP
SE DECISION MADE: 13-DEC-2001
510(k) STATEMENT

AUTOGENESIS, INC.
ATTN: JAMES EDWARDS
8700 OLD HARFORD RD.
BALTIMORE, MD 21234
510(k) NO: K013818
PHONE NO : 410-665-2017
DEVICE: AUTOGENESIS AUTOMATOR, MODEL M1000
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

AVID N.I.T., INC.
NIT METAL HUB LUTZ EPIDURAL NEEDLE, MODEL RM2035L
ATTN: SCOTT HENDERSON
390 SCARLET BLVD.
OLDSMAR, FL 34677
510(k) NO: K013231
PHONE NO : 813-818-8705
DEVICE: AVID-NIT PLASTIC HUB LUTZ EPIDURAL NEEDLE,MODEL RP2035L, AVID-
SE DECISION MADE: 03-DEC-2001
510(k) STATEMENT

BAXTER HEALTHCARE CORP.
5C8310, 5C8302, 5C4471, 5C4469
ATTN: DAVID E CURTIN
1620 WAUKEGAN RD.
MPGR-A2E
MCGAW PARK, IL 60085
510(k) NO: K012988
PHONE NO : 847-473-6079
DEVICE: HOMECHOICE PERSONAL CYCLER PERITONEAL DIALYSIS SYSTEM, MODELS
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYER CORP.
ATTN: KENNETH T EDDS
511 BENEDICT AVE.
TARRYTOWN, NY 10591-5097
510(k) NO: K012337
PHONE NO : 914-524-2446
DEVICE: BAYER ADVIA IMS SYSTEM; C-REACTIVE PROTEIN SYSTEM
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYER CORP.
ATTN: KENNETH T EDDS
511 BENEDICT AVE.
TARRYTOWN, NY 10591-5097
510(k) NO: K013568
PHONE NO : 914-524-2446
DEVICE: CEA ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEM
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYER DIAGNOSTICS CORP.
ATTN: BARBARA PREISEL-SIMMONS
63 NORTH STREET
MEDFIELD, MA 02052
510(k) NO: K012183
PHONE NO : 508-359-7711
DEVICE: BAYER DIAGNOSTICS ADVIA CENTAUR TOXOPLASMA IGG ASSAY
SE DECISION MADE: 27-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYER DIAGNOSTICS CORP.
ATTN: KENNETH T EDDS
511 BENEDICT AVE
TARRYTOWN, NY 10591-5097
510(k) NO: K013406
PHONE NO : 914-524-2446
DEVICE: ADVIA CENTAUR HOMOCYSTEINE ASSAY
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BAYER DIAGNOSTICS CORP.
ATTN: KENNETH T EDDS
511 BENEDICT AVE
TARRYTOWN, NY 10591-5097
510(k) NO: K013606
PHONE NO : 914-524-2446
DEVICE: ACS 180 HOMOCYSTEINE ASSAY
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
IN CALIBRATOR
ATTN: MARY BETH TANG
200 SOUTH KRAEMER BLVD.,W-104
BREA, CA 92822-8000
510(k) NO: K013076
PHONE NO : 714-961-3777
DEVICE: SYNCHRON SYSTEMS VANCOMYCIN REAGENT; SYNCHRON SYSTEMS VANCOMYC
SE DECISION MADE: 12-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ATTN: LOURDES COBA
11800 SW 147TH AVENUE
MIAMI, FL 33196-2500
510(k) NO: K013842
PHONE NO : 305-380-4079
DEVICE: IMMUNO-TROL LOW CELLS
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC.
ND LX20 PRO)
ATTN: ANNETTE HELLIE
200 SOUTH KRAEMER BLVD.
BREA, CA 92822
510(k) NO: K014034
PHONE NO : 714-993-8767
DEVICE: MODIFICATION TO SYNCHRON LX CLINICAL CHEMISTRY SYSTEMS (LX20 A
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

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

BIOMET MANUFACTURING, INC.
ATTN: SARA B SHULTZ
P.O. BOX 587
WARSAW, IN 46581-0587
510(k) NO: K012469
PHONE NO : 219-267-6639
DEVICE: RESORBABLE NO PROFILE SCREW AND WASHER
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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| BIOMET ORTHOPEDICS, , INC.<br>ATTN: SARA B SHULTZ<br>P.O. BOX 587<br>WARSAW, IN 46582 | 510(k) NO: K013534<br>PHONE NO : 219-267-6639 | DEVICE: SELF-COUNTERSINKING BONE SCREW<br>SE DECISION MADE: 17-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOMET ORTHOPEDICS, , INC.<br>ATTN: TRACY J BICKEL<br>P.O. BOX 587<br>WARSAW, IN 46581-0587 | 510(k) NO: K013657<br>PHONE NO : 219-267-6639 | DEVICE: MODIFICATION TO: BIOMET HUMERAL CABLE PLATES<br>SE DECISION MADE: 03-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOMET, INC.<br>ATTN: MARY VERSTYNEN<br>AIRPORT INDUSTRIAL PARK<br>P.O. BOX 587<br>WARSAW, IN 46581-0587 | 510(k) NO: K993836<br>PHONE NO : 219-267-6639 | DEVICE: GENERATION 4 BONE CEMENT<br>SE DECISION MADE: 19-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOMET, INC.<br>ATTN: TRACY J BICKEL<br>AIRPORT INDUSTRIAL PARK<br>P.O. BOX 587<br>WARSAW, IN 46581-0587 | 510(k) NO: K011139<br>PHONE NO : 219-372-1761 | DEVICE: LORENZ LACTOSORB PANELS AND FASTENERS<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOMET, INC.<br>ATTN: SARA BAILEY SHULTZ<br>P.O. BOX 587<br>WARSAW, IN 46581-0587 | 510(k) NO: K011451<br>PHONE NO : 219-372-1568 | DEVICE: REUNITE FUSION SCREW<br>SE DECISION MADE: 10-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOMET, INC.<br>ATTN: SARA B SHULTZ<br>56 EAST BELL DRIVE<br>PO BOX 587<br>WARSAW, IN 46582 | 510(k) NO: K012569<br>PHONE NO : 219-267-6639 | DEVICE: MODIFICATION TO: INJECTABLE MIMIX<br>SE DECISION MADE: 21-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOMET, INC.<br>ATTN: SARA B SHULTZ<br>56 EAST BELL DRIVE<br>PO BOX 587<br>WARSAW, IN 46581-0578 | 510(k) NO: K012572<br>PHONE NO : 219-267-6639 | DEVICE: SOFT TISSUE SCREW AND WASHER<br>SE DECISION MADE: 03-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOPLATE, INC.<br>ATTN: CAROL E JONES<br>6911 MELROSE AVE.<br>LOS ANGELES, CA 90038 | 510(k) NO: K013050<br>PHONE NO : 323-549-9500 | DEVICE: THE BIOPLATE ZIP CRANIOTOMY FIXATION SYSTEM<br>SE DECISION MADE: 10-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| BIOPLATE, INC.<br>ATTN: CAROL E JONES<br>6911 MELROSE AVE.<br>LOS ANGELES, CA 90038 | 510(k) NO: K013055<br>PHONE NO : 323-549-9500 | DEVICE: THE BIOPLATE BIOCLIP CRANIOTOMY FIXATION SYSTEM<br>SE DECISION MADE: 07-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

BIOTEQUE AMERICA, INC.
ATTN: DENIS DORSEY
340 EAST MAPLE AVE., #204-C
LANGHORNE, PA 19047

510(k) NO: K013289
PHONE NO : 215-750-8071

DEVICE: BIOTEQUE VAGINAL PESSARIES
SE DECISION MADE: 27-DEC-2001
510(k) STATEMENT

BKG OPTHALMICS USA, INC.
ATTN: ART WARD
962 ALLEGRO LANE
APOLLO BEACH, FL 33572

510(k) NO: K013151
PHONE NO : 813-645-2855

DEVICE: ASMOTOM AUTOMATED TREPHINE SYSTEM
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BONUTTI RESEARCH, INC.
ATTN: PATRICK BALSMANN
2600 SOUTH RANEY
P.O. BOX 1367
EFFINGHAM, IL 62401

510(k) NO: K013177
PHONE NO : 217-342-3412

DEVICE: MULITTAK SUTURE SNAP SYSTEM
SE DECISION MADE: 19-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC
ATTN: ANDREA L RUTH
2710 ORCHARD PARKWAY
SAN JOSE, CA 95134

510(k) NO: K013866
PHONE NO : 408-895-3625

DEVICE: CONVOY ADVANCED DELIVERY SHEATH KIT
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BOSTON SCIENTIFIC CORP.
ATTN: JENNIFER BOLTON
ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760

510(k) NO: K011889
PHONE NO : 508-652-5972

DEVICE: ULTRA -THIN SDS BALLOON DILATATION CATHETER
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013789

PHONE NO : 510-440-7604

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

SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

BREG, INC.
ATTN: KATHLEEN BARBER
2611 COMMERCE WAY
VISTA, CA 92083

510(k) NO: K013928
PHONE NO : 760-599-3000

DEVICE: PAIN CARE 3200
SE DECISION MADE: 03-DEC-2001
510(k) STATEMENT

BYPASS LTD.
064, CORLINK AAD (2.0 TO 4.0 MM OUTER DIAMETER VESSELS), M
ATTN: JONATHAN S KAHAN
555 THIRTEENTH STREET NW
WASHINGTON, DC 20004-1109

510(k) NO: K011589
PHONE NO : 202-637-5910

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

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

CAIRD TECHNOLOGY
ATTN: JAMES H BROWN
205 CAMDEN CHASE
COLUMBIA, SC 29223

510(k) NO: K012686
PHONE NO : 803-736-1289

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

CAIRE, INC.
ATTN: ROGER BRIESE
3505 COUNTY RD. 42 WEST
BURNSVILLE, MN 55306-3803

510(k) NO: K013251
PHONE NO : 952-882-5071

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

CAMBRIDGE DIAGNOSTICS IRELAND, LTD
ATTN: AVRIL MURRAY
MERVUE BUSINESS PARK
GALWAY,

510(k) NO: K013907
PHONE NO : 011 353 91757534

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

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

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

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

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

510(k) NO: K013753

PHONE NO : 909-465-9188

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

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

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

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

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

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

510(k) NO: K013901
PHONE NO : 508-285-1700

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

CIBA VISION CORP.
ATTN: STEVEN DOWDLEY
11460 JOHNS CREEK PKWY.
DULUTH, GA 30097

510(k) NO: K012731
PHONE NO : 687-415-3897

DEVICE: SOLO-CARE PLUS MULTIPURPOSE SOLUTION
SE DECISION MADE: 26-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CIBA VISION CORP.
ATTN: STEVEN DOWDLEY
11460 JOHNS CREEK PKWY.
DULUTH, GA 30097

510(k) NO: K013512
PHONE NO : 687-415-3897

DEVICE: AOSEPT CLEAR CARE CLEANING AND DISINFECTING SOLUTION
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CIRCON VIDEO
33, MR-642) URETEROSCOPES, MRO-7 SERIES (MRO-733) URETEROS
ATTN: WAYNE B STERNER
6500 HOLLISTER AVE.
SANTA BARBARA, CA 93117

510(k) NO: K011849
PHONE NO : 805-685-5100

DEVICE: MICRO-6-SERIES (MR-6, MR-6L) URETEROSCOPES, MRO-6 SERIES (MR-6

SE DECISION MADE: 10-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

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

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

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

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

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

CODMAN & SHURTLEFF, INC.
ATTN: KATHRYN WUNDER
325 PARAMOUNT DR.
RAYNHAM, MA 02767-0350

510(k) NO: K013877
PHONE NO : 508-880-8351

DEVICE: CODMAN SLIM-LOC SYSTEM
SE DECISION MADE: 19-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

COLTENE/WHALEDENT, INC.
ATTN: H.J. VOGELSTEIN
750 CORPORATE DR.
MAHWAH, NJ 07430-2009

510(k) NO: K013400
PHONE NO : 201-512-8000

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

COMPUTER MOTION, INC.
ATTN: DAVID U THOMAS
130 CREMONA DRIVE, SUITE B
GOLETA, CA 93117

510(k) NO: K013804
PHONE NO : 805-968-9600

DEVICE: SOCRATES ROBOTIC TELEMONITORING SYSTEM
SE DECISION MADE: 10-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

COMPUTERIZED MEDICAL SYSTEMS, INC.
ATTN: MICHAEL A PARSONS
1145 CORPORATE LAKE DR.
ST. LOUIS, MO 63132-1716

510(k) NO: K013112
PHONE NO : 314-993-0003

DEVICE: FOCAL SIM
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

CONTACT COLOR SRL
ATTN: MARIA E DONAWA
VIA FONTE DI FAUNO, 22
ROME,

510(k) NO: K011893
PHONE NO : 390 657 82665

DEVICE: COSMETICA (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

COOK VASCULAR, INC.
ATTN: THOMAS J KARDOS
RT. 66, RIVER RD.
P.O. BOX 529
LEECHBURG, PA 15656-0529

510(k) NO: K002958
PHONE NO : 724-845-8621

DEVICE: SHAPEABLE DOPPLER FLOW PROBE
SE DECISION MADE: 18-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

COOK, INC.
ATTN: HEIDI MASTEN
925 SOUTH CURRY PIKE
P.O. BOX 489
BLOOMINGTON, IN 47402

510(k) NO: K013916
PHONE NO : 812-339-2235

DEVICE: MELKER EMERGENCY CRICOTHYROTOMY CATHETER SET
SE DECISION MADE: 20-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

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|---|---|---|
| CRESCO TI SYSTEMS AB<br>ATTN: PER E NILSSON<br>350 GLEN COVE AVENUE<br>GLEN HEAD, NY 11545 | 510(k) NO: K981052<br>PHONE NO : 516-759-6390 | DEVICE: CRESCO TI IMPLANT CONCEPT<br>SE DECISION MADE: 18-DEC-2001<br>510(k) STATEMENT |
| CSIST<br>ATTN: CARL ALLETO<br>1100 LAKEVIEW BLVD.<br>DENTION, TX 76208 | 510(k) NO: K012327<br>PHONE NO : 214-262-4209 | DEVICE: CSIST DICOM GATEWAY/IMAGE MANAGER<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| CYBERMED, INC.<br>ATTN: GARY J ALLSEBROOK<br>16303 PANORAMIC WAY<br>SAN LEANDRO, CA 94578-1116 | 510(k) NO: K013878<br>PHONE NO : 510-276-2648 | DEVICE: CYBERMED, INC., V-WORKS<br>SE DECISION MADE: 07-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DADE MICROSCAN, INC.<br>ATTN: CYNTHIA VAN DUKER<br>1584 ENTERPRISE BLVD.<br>WEST SACRAMENTO, CA 95691 | 510(k) NO: K013423<br>PHONE NO : 916-374-3105 | DEVICE: MICROSCAN DRIED GRAM NEGATIVE OVERNIGHT MIC/COMBO PANELS<br>SE DECISION MADE: 12-DEC-2001<br>510(k) STATEMENT |
| DATEX-OHMEDA<br>ATTN: JOEL KENT<br>86 PILGRIM ROAD<br>NEEDHAM, MA 02492 | 510(k) NO: K013246<br>PHONE NO : 781-449-8685 | DEVICE: DATEX-OHMEDA S/5 NETWORK AND CENTRAL '01<br>SE DECISION MADE: 11-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DEMITE LIMITED<br>ATTN: WILLIAM H.E. VON OEHSEN<br>1001 PENNSYLVANIA AVE.<br>NW 6TH FLOOR<br>WASHINGTON, DC 20004 | 510(k) NO: K001003<br>PHONE NO : 202-347-0066 | DEVICE: Z-NET<br>SE DECISION MADE: 10-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DENKA SEIKEN'S<br>ATTN: SEIYA SATO<br>3-4-2 NIHONBASHI<br>KAYABACHO, CHUO-KU<br>TOKYO, | 510(k) NO: K011958<br>PHONE NO : 033 669 421 | DEVICE: CRP-LATEX (II) SEIKEN HIGH SENSITIVITY ASSAY KIT<br>SE DECISION MADE: 04-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DEPUY ORTHOPAEDICS, INC.<br>ATTN: MARCIA J ARENTZ<br>700 ORTHOPAEDIC DR.<br>P.O. BOX 988<br>WARSAW, IN 46581-0988 | 510(k) NO: K013352<br>PHONE NO : 219-371-4944 | DEVICE: SUMMIT CEMENTED HIP PROSTHESIS<br>SE DECISION MADE: 17-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DEPUY ORTHOPAEDICS, INC.<br>ATTN: MARCIA J ARENTZ<br>700 ORTHOPAEDIC DR.<br>WARSAW, IN 46581-0988 | 510(k) NO: K013430<br>PHONE NO : 219-371-4944 | DEVICE: ACE BIO WIN TIBIAL NAILING SYSTEM<br>SE DECISION MADE: 17-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

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| DEPUY ORTHOPAEDICS, INC.<br>ATTN: MARCIA J ARENTZ<br>700 ORTHOPAEDIC DR.<br>WARSAW, IN 46581-0988 | 510(k) NO: K013563<br>PHONE NO : 219-371-4944 | DEVICE: LONG TROCHANTERIC NAIL SYSTEM<br>SE DECISION MADE: 27-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DESIGNS FOR VISION, INC.<br>ATTN: AMY GRUMET-AVALLONE<br>760 KOEHLER AVE.<br>RONKONKOMA, NY 11779 | 510(k) NO: K013880<br>PHONE NO : 631-585-3300 | DEVICE: DAYLITE XENON LIGHT SOURCES<br>SE DECISION MADE: 07-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DIAGNOSTIC CHEMICALS LTD.<br>ATTN: NANCY OLSCAMP<br>16 MOCARVILLE STREET<br>CHARLOTTETOWN, | 510(k) NO: K013178<br>PHONE NO : 902 566 1396 | DEVICE: DC-UIBC-CO2-CAL, MODEL SE-153<br>SE DECISION MADE: 18-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DIAMEDIX CORP.<br>ATTN: LYNNE STIRLING<br>2140 NORTH MIAMI AVE.<br>MIAMI, FL 33127 | 510(k) NO: K013628<br>PHONE NO : 305-324-2354 | DEVICE: DIAMEDIX IS-ANTI-B2 GLYCOPROTEIN I IGG/IGM TEST SYSTEM<br>SE DECISION MADE: 21-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DIAMOND DIAGNOSTICS, INC.<br>ATTN: LINDA M STUNDTNER<br>331 FISKE STREET<br>HOLLISTON, MA 01746 | 510(k) NO: K013850<br>PHONE NO : 508-429-0450 | DEVICE: STANDARD A, STANDARD B, STANDARD C, CAL, SLOPE<br>SE DECISION MADE: 21-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DISC-O-TECH MEDICAL TECHNOLOGIES,<br>TEM<br>ATTN: ELAD MAGAL<br>3 HASADNAOT<br>HERZELIA, | 510(k) NO: K013449<br>PHONE NO : 972 9 9511511 | DEVICE: MODIFICATION TO FIXION INTERLOCKING INTRAMEDULLARY NAILING SYS<br>SE DECISION MADE: 19-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| DOCTOR'S RESEARCH GROUP, INC.<br>ATTN: RICHARD DESLAURIERS<br>50 ALTAIR AVENUE<br>PLYMOUTH, CT 06782 | 510(k) NO: K013786<br>PHONE NO : 860-283-1479 | DEVICE: DRG ORTHOHEX SS BONE SCREW<br>SE DECISION MADE: 17-DEC-2001<br>510(k) STATEMENT |
| DOUGLAS C. YOON, DDS<br>ATTN: DOUGLAS C YOON<br>3940 LAUREL CANYON BLVD. #147<br>STUDIO CITY, CA 91604 | 510(k) NO: K013271<br>PHONE NO : 310-702-3185 | DEVICE: DXS DIGITAL X-RAY SYSTEM<br>SE DECISION MADE: 13-DEC-2001<br>510(k) STATEMENT |
| DRAGER MEDIZINTECHNIK GMBH<br>ATTN: JAMES J BRENNAN<br>3135 QUARRY ROAD<br>TELFORD, PA 18969 | 510(k) NO: K010793<br>PHONE NO : 215-721-5400 | DEVICE: OXYLOG 1000, MODEL 2M86840<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

DRUG FREE ENTERPRISES
ATTN: PERRY RUCKER
1627 S GRANVILLE AVE. SUITE 3
WEST LOS ANGELES, CA 90025

510(k) NO: K012390
PHONE NO : 310-415-7093

DEVICE: NO STEP ON SITE DEUG TEST CUP
SE DECISION MADE: 18-DEC-2001
510(k) STATEMENT

EASTMAN KODAK COMPANY
ATTN: JUDITH A WALLACE
1669 LAKE AVE.
ROCHESTER, NY 14652

510(k) NO: K013686
PHONE NO : 716-724-6111

DEVICE: KODAK DIRECTVIEW TABLETOP CASSETTE
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

EBI, L.P.
ATTN: FREDERIC TESTA
100 INTERPACE PKWY.
PARSIPPANY, NJ 07054-1079

510(k) NO: K013739
PHONE NO : 973-299-9300

DEVICE: MODIFICATION TO EBI XFIX DFS SYSTEM
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ELCARE INNOVATIONS, INC.
ATTN: ELROY T CANTRELL
7101 STEPHENSON-LEVEY RD
BURLESON, TX 76028

510(k) NO: K010526
PHONE NO : 817-483-2310

DEVICE: MODIFICATION TO THE GRIP
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ELEKTA INSTRUMENT AB
ATTN: CAROL PATTERSON
21911 ERIE LANE
LAKE FOREST, CA 92630

510(k) NO: K013861
PHONE NO : 949-462-0900

DEVICE: MODIFICATION TO LEKSELL SURGIPLAN WITH ATLASPACE
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ENCORE ORTHOPEDICS, INC.
ATTN: JOANNA DROEGE
9800 METRIC BLVD.
AUSTIN, TX 78758

510(k) NO: K003324
PHONE NO : 512-834-6255

DEVICE: PLASMA SPRAYED SHOULDER
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ETHICON ENDO-SURGERY, INC.
ATTN: GEORGIA C ABERNATHY
4545 CREEK RD.
CINCINNATI, OH 45242-2839

510(k) NO: K013413
PHONE NO : 513-337-3179

DEVICE: MICROMARK II TISSUE MARKER,MODEL C1535
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ETHICON ENDO-SURGERY, INC.
ATTN: LINDA HILL
4545 CREEK ROAD
CINCINNATI, OH 45242

510(k) NO: K013493
PHONE NO : 513-337-7623

DEVICE: INDIGO OPTIMA LASER SYSTEM
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

EVENFLO COMPANY, INC.
ATTN: MATTHEW G MCCARTY
1000 EVENFLO DRIVE
P.O. BOX 709
CANTON, GA 30114

510(k) NO: K013226
PHONE NO : 770-704-2000

DEVICE: EVENFLO COMFORT EASE MANUAL BREAST PUMP KIT
SE DECISION MADE: 20-DEC-2001

510(k) STATEMENT

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| EXACTECH, INC.<br>ATTN: ROBERT PAXSON<br>2320 N.W. 66TH CT.<br>GAINESVILLE, FL 32653 | 510(k) NO: K013211<br>PHONE NO : 352-377-1140 | DEVICE: MODIFICATION TO: ACUMATCH L-SERIES BIPOLAR ENDOPROSTHESIS<br>SE DECISION MADE: 05-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| EXELINT INTL. CO.<br>ATTN: ARMAND HAMID<br>5840 WEST CENTINELA AVE.<br>LOS ANGELES, CA 90045 | 510(k) NO: K013037<br>PHONE NO : 310-649-0707 | DEVICE: EXCEL A.V FISUTAL NEEDLE SET<br>SE DECISION MADE: 07-DEC-2001<br>510(k) STATEMENT |
| FELTON INTERNATIONAL, INC.<br>ATTN: ALAN FELTON<br>8210 MARSHALL DRIVE<br>LENEXA, KS 66214 | 510(k) NO: K013256<br>PHONE NO : 913-599-1590 | DEVICE: BI-3M NEEDLE-FREE INJECTOR SYSTEM<br>SE DECISION MADE: 07-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| FIRST MEDICAL, INC.<br>ATTN: GREG HOLLAND<br>3722 AVE. SAUSALITO<br>IRVINE, CA 92606 | 510(k) NO: K014024<br>PHONE NO : 949-262-0411 | DEVICE: MODIFICATION TO ALPHA DX SYSTEM<br>SE DECISION MADE: 18-DEC-2001<br>510(k) STATEMENT |
| FLORIDA OPTICAL ENGINEERING, INC.<br>ATTN: RICHARD A GRIFFIN<br>13709 PROGRESS BLVD., BOX 14<br>ALACHUA, FL 32615 | 510(k) NO: K013445<br>PHONE NO : 386-472-2710 | DEVICE: OSPREY SPHERICAL AND TORIC MULTIFOCAL SOFT CONTACT LENSES<br>SE DECISION MADE: 26-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| FOTONA D.D.<br>ATTN: MOJCA VALJAVEC<br>STEGNE 7,<br>LJUBLJANA, | 510(k) NO: K011939<br>PHONE NO : 386 151 11215 | DEVICE: FOTONA DUALIS, FOTONA DUALIS PLUS<br>SE DECISION MADE: 27-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| FRIADENT GMBH<br>ATTN: CAROL PATTERSON<br>21911 ERIE LANE<br>LAKE FOREST, CA 92630 | 510(k) NO: K013438<br>PHONE NO : 949-462-0900 | DEVICE: FRIALIT-2 ESTHETICBASE ABUTMENT<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| FUJIFILM MEDICAL SYSTEM U.S.A., IN<br>ATTN: JOSEPH M AZARY<br>419 WEST AVE.<br>STAMFORD, CT 06902 | 510(k) NO: K013218<br>PHONE NO : 203-327-6485 | DEVICE: FUJI SPEED SUITE, FUJI SPEED SUTE PHASE II<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| FUKUDA DENSHI USA, INC.<br>ATTN: LARRY WALKER<br>17725 N.E. 65TH ST., BLDG. C<br>REDMOND, WA 98052-4911 | 510(k) NO: K013273<br>PHONE NO : 425-881-7737 | DEVICE: FUKUDA DENSHI MODEL HG-500, PULSE OXIMETER MODULE<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| GENERAL ELECTRIC MEDICAL SYSTEMS<br>ATTN: D. DUERSTELER<br>3000 NORTH GRANDVIEW BLVD.<br>WAUKESHA, WI 53188 | 510(k) NO: K014058<br>PHONE NO : 262-317-9463 | DEVICE: ENTEGRA PE PERSONAL DIGITAL ASSISTANT<br>SE DECISION MADE: 21-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

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| GIMMI GMBH<br>ATTN: DAGMAR MASER<br>AMSTEL 320-I<br>AMSTERDAM, | 510(k) NO: K012660<br>PHONE NO : 312 042 89591 | DEVICE: GIMMI'ALPHA' ENDOSCOPES & ACCESSORIES<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| GLUSTITCH, INC.<br>ATTN: DON BLACKLOCK<br>#307 7188 PROGRESS WAY<br>DELTA, B.C., | 510(k) NO: K013446<br>PHONE NO : 800 667 2130 | DEVICE: GLUSITE, MODEL GLU002<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| GOLDEN TECHNOLOGIES, INC.<br>ATTN: FRED KIWAK<br>401 BRIDGE ST.<br>OLD FORGE, PA 18518 | 510(k) NO: K012258<br>PHONE NO : 570-451-7477 | DEVICE: COMPANION MODEL 221, 321, 421<br>SE DECISION MADE: 03-DEC-2001<br>510(k) STATEMENT |
| GUIDANT CORP.<br>IC COATING<br>ATTN: JENNIFER P RIGGS<br>26531 YNEZ RD.<br>TEMECULA, CA 92591-4628 | 510(k) NO: K013092<br><br>PHONE NO : 909-914-4581 | DEVICE: HI-TOQUE WHISPER LS AND MS GUIDE WIRE WITH HYDROCOAT HYDROPHIL<br><br>SE DECISION MADE: 13-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| GUIDANT CORP.<br>ATTN: NANCY E RALSTON<br>26531 YNEZ RD.<br>TEMECULA, CA 92591-4628 | 510(k) NO: K013638<br>PHONE NO : 909-914-6654 | DEVICE: MODIFICATION TO VIKING OPTIMA GUIDING CATHETER<br>SE DECISION MADE: 04-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| H.S. HOSPITAL SERVICES S.P.A.<br>ATTN: LUCIO IMPROTA<br>10147 UMBERLAND PLACE<br>BOCA RATON, FL 33428 | 510(k) NO: K013069<br>PHONE NO : 561-477-1671 | DEVICE: BIOSPEED<br>SE DECISION MADE: 12-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| H.S. HOSPITAL SERVICES S.P.A.<br>ATTN: LUCIO IMPROTA<br>10147 UMBERLAND PLACE<br>BOCA RATON, FL 33428 | 510(k) NO: K013070<br>PHONE NO : 561-477-1671 | DEVICE: JAMSHIDI BIOPSY NEEDLE<br>SE DECISION MADE: 12-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| H.S. HOSPITAL SERVICES S.P.A.<br>ATTN: LUCIO IMPROTA<br>10147 UMBERLAND PLACE<br>BOCA RATON, FL 33428 | 510(k) NO: K013071<br>PHONE NO : 561-477-1671 | DEVICE: SECURCUT ASPIRATION BIOPSY NEEDLE<br>SE DECISION MADE: 12-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HAND INNOVATIONS, INC.<br>ATTN: AL WEISENBORN<br>8905 SW 87TH AVENUE<br>MIAMI, FL 33176-2227 | 510(k) NO: K013424<br>PHONE NO : 305-829-3437 | DEVICE: INTRAMEDULLARY FIXATION SYSTEM FOR THE HAND<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

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| HELENA LABORATORIES<br>ATTN: PATRICIA FRANKS<br>P.O. BOX 752<br>1530 LINDBERGH DRIVE<br>BEAUMONT, TX 77794 | 510(k) NO: K013466<br>PHONE NO : 409-842-3714 | DEVICE: SPIFE 2000/3000 LIPOPROTEIN; MODEL# 3340, 3341, 3342, 3343<br>SE DECISION MADE: 21-DEC-2001<br><br>510(k) STATEMENT |
| HELIO MEDICAL SUPPLIES, INC.<br>ATTN: YI FEN CHANG<br>606 CHARCOT AVE.<br>SAN JOSE, CA 95131 | 510(k) NO: K012583<br>PHONE NO : 408-433-3355 | DEVICE: ACUGLIDE BRAND ACUPUNCTURE NEEDLES<br>SE DECISION MADE: 11-DEC-2001<br>510(k) STATEMENT |
| HERBO MEDEX INTERNATIONAL, INC.<br>ATTN: RICHARD KEEN<br>1151 HOPE STREET<br>STAMFORD, CT 06907 | 510(k) NO: K004008<br>PHONE NO : 203-329-2700 | DEVICE: STRESS GUARD, MODEL HERDEV1<br>SE DECISION MADE: 13-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HOLLISTER, INC.<br>ATTN: JOSEPH S TOKARZ<br>2000 HOLLISTER DR.<br>LIBERTYVILLE, IL 60048 | 510(k) NO: K013141<br>PHONE NO : 847-680-2849 | DEVICE: MICROGYN PLUS STIMULATION DEVICE<br>SE DECISION MADE: 19-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HOWMEDICA OSTEONICS<br>ATTN: KAREN ARIEMMA<br>59 ROUTE 17<br>ALLENDALE, NJ 07401-1677 | 510(k) NO: K013772<br>PHONE NO : 201-825-4900 | DEVICE: MODIFICATION TO HOFFMANN II MICRO EXTERNAL FIXATION SYSTEM<br>SE DECISION MADE: 03-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HOWMEDICA OSTEONICS CORP.<br>COATING<br>ATTN: MARGARET F CROWE<br>59 ROUTE 17<br>ALLENDALE, NJ 07401-1677 | 510(k) NO: K013475<br><br>PHONE NO : 201-934-4359 | DEVICE: TRIDENT POROUS TITANIUM ACETABULAR COMPONENT WITH PERI-APATITE<br><br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HOWMEDICA OSTEONICS CORP.<br>ATTN: JENNIFER A DAUDELIN<br>59 ROUTE 17<br>ALLENDALE, NJ 07070-2584 | 510(k) NO: K013676<br>PHONE NO : 201-934-4354 | DEVICE: TRIDENT HEMISPHERICAL ACETABULAR SHELLS<br>SE DECISION MADE: 05-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HOWMEDICA OSTEONICS CORP.<br>ATTN: KAREN ARIEMMA<br>59 ROUTE 17<br>ALLENDALE, NJ 07401-1677 | 510(k) NO: K013688<br>PHONE NO : 201-825-4900 | DEVICE: MODIFICATION TO XIA SPINAL SYSTEM<br>SE DECISION MADE: 05-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| HOWMEDICA OSTEONICS CORP.<br>ATTN: KAREN ARIEMMA<br>59 ROUTE 17<br>ALLENDALE, NJ 07401-1677 | 510(k) NO: K013823<br>PHONE NO : 201-760-8187 | DEVICE: XIA SPINAL SYSTEM<br>SE DECISION MADE: 19-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

HUMANA USA, INC.
ATTN: H.N. DUNNING
8309 BRYANT DRIVE
BETHESDA, MD 20817

510(k) NO: K012199
PHONE NO : 301-229-2138

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

HUMMINGBIRD MEDICAL TECHNOLOGY, L.
ATTN: GEOFFREY HSU
1427 GREENBRIAR DR.
ALLEN, TX 75013

510(k) NO: K012501
PHONE NO : 214-284-5433

DEVICE: H.M.T. ACUPUNCTURE NEEDLE
SE DECISION MADE: 11-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

ICS MEDICAL
ATTN: ROBERT M SIMENSON
125 COMMERCE DR.
SCHAUMBURG, IL 60173-5329

510(k) NO: K013060
PHONE NO : 800-289-2150

DEVICE: ICS MEDICAL MODEL VG-30 VIDEO GOGGLES
SE DECISION MADE: 10-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

IMAGYN MEDICAL TECHNOLOGIES, INC.
ATTN: JULIE POWELL
8850 M-89
RICHLAND, MI 49083

510(k) NO: K010166
PHONE NO : 616-629-2787

DEVICE: IMAGYN ISOSLEEVE / ISOSTAR NEEDLE SYSTEM
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

IMPLANT INNOVATIONS, INC.
ATTN: JACQUELYN A HUGHES
4555 RIVERSIDE DR.
PALM BEACH GARDENS, FL 33410

510(k) NO: K013570
PHONE NO : 561-776-6819

DEVICE: OSSEOTITE DENTAL IMPLANTS
SE DECISION MADE: 17-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

IN-X CORP.
ATTN: CHARLIE HENRY
6753 EAST 47TH AVENUE
UNIT D
DENVER, CO 80216

510(k) NO: K004047
PHONE NO : 303-574-3115

DEVICE: HOME-AWAY SYSTEM
SE DECISION MADE: 18-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

INNOVATIVE GLOVES CO; LTD
N CONCENT LABEL CLAIM
ATTN: RAJEEV K SOOD
11 CHOTEVITTAYAKUL 3 RD.
HATYAI, SONGKHLA,

510(k) NO: K013333

PHONE NO : 661 897 9821

DEVICE: LATEX EXAMINATION GLOVES POWDERFREE POLYMER COATED WITH PROTEI

SE DECISION MADE: 07-DEC-2001
510(k) STATEMENT

INSTITUT STRAUMANN AG
ATTN: LINDA JALBERT
RESERVOIR PLACE
1601 TRAPELO ROAD
WALTHAM, MA 02451

510(k) NO: K013798
PHONE NO : 800-448-8168

DEVICE: PROSTHETIC ACCESSORIES TO THE ITI DENTAL IMPLANT SYSTEM
SE DECISION MADE: 19-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

INVACARE CORP.
ATTN: RAE A FARROW
ONE INVACARE WAY
P.O. BOX 4028
ELYRIA, OH 44036-2125

510(k) NO: K013516
PHONE NO : 440-329-6356

DEVICE: INVACARE ELEVATING SEAT OPTION ESS6
SE DECISION MADE: 13-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

JANIN GROUP, INC.
ATTN: JOHN A NAVIS
505 WESTON RIDGE DR.
NAPERVILLE, IL 60563-3932

510(k) NO: K013017
PHONE NO : 630-428-4143

DEVICE: MEDIGROUP KEY TUBE
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013698
PHONE NO : 305-418-2320

DEVICE: AST (SGOT)
SE DECISION MADE: 21-DEC-2001
510(k) STATEMENT

JOSTRA AG
ATTN: KATHLEEN JOHNSON
478 MEDIA ROAD
OXFORD, PA 19363

510(k) NO: K013939
PHONE NO : 610-932-7738

DEVICE: JOSTRA FLOWPROBE FP-32E
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

K-SYSTEMS, KIVEX BIOTEC LTD.
B-01
ATTN: JACOB MOLLENBACH
KLINTEHOJ VAENGE 21
BIRKEROD,

510(k) NO: K013401

PHONE NO : 454 599 5600

DEVICE: K-SYSTEMS CULTURE BAG SEALER AND CULTURE BAGS TYPE CBS-1 AND C

SE DECISION MADE: 14-DEC-2001
510(k) STATEMENT

KIM INSTITUTE FOR REHABILITATION M
ATTN: DONALD F GRABARZ
7651 S. 700 WEST
SUITE 105
SALT LAKE CITY, UT 84047

510(k) NO: K011691
PHONE NO : 801-233-0075

DEVICE: KIMSTIM AURICULAR ELECTRODE
SE DECISION MADE: 27-DEC-2001

510(k) STATEMENT

KOON SENG SDN.BHD
CONTENT LABELING CLAIM (200 MICROGRAMS OR LESS)
ATTN: LIM WENG HENG
PTD 3274 BATU 4 1/2
JALAN BAKRI
MUAR JOHOR,

510(k) NO: K013537

PHONE NO : 606 986 8446

DEVICE: ROYAL IMPERIAL POWDERED LATEX EXAMINATION GLOVES WITH PROTEIN

SE DECISION MADE: 07-DEC-2001

510(k) STATEMENT

LARES RESEARCH, INC.
TPRO OR POCKETPRO S4")
ATTN: THOMAS H LOUISELL
295 LOCKHEED AVE.
CHICO, CA 95973

510(k) NO: K011960

PHONE NO : 530-345-1767

DEVICE: LARES RESEARCH SUNLASE 800P LASER SYSTEM (TO BE SOLD AS "POCKE

SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

LINVATEC CORP.
ATTN: LAURA D SENEFF
11311 CONCEPT BLVD.
LARGO, FL 33773-4908

510(k) NO: K013553
PHONE NO : 727-399-5234

DEVICE: PRE-LOADED ULTRAFIX RC
SE DECISION MADE: 19-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

LUMENIS
ATTN: C. ROBERT PAYNE JR.
1249 QUARRY LANE
SUITE 100
PLEASANTON, CA 94566-3403

510(k) NO: K011197
PHONE NO : 925-249-8034

DEVICE: LIGHTSHEER UV-B PHOTOTHERAPY EQUIPMENT
SE DECISION MADE: 14-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

MACROPORE, INC.
ATTN: KENNETH K KLEINHENZ
6740 TOP GUN ST.
SAN DIEGO, CA 92121
510(k) NO: K012025
PHONE NO : 858-458-0900
DEVICE: MACROPORE TS ANTI-ADHESION FILM
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MALLINCKRODT, INC.
ATTN: ANTHONY MULLIN
675 MCDONNELL BLVD.
BLDG. 10-2-N
ST. LOUIS, MO 63134
510(k) NO: K003075
PHONE NO : 314-645-3049
DEVICE: KNIGHTSTAR 330 VENTILATOR
SE DECISION MADE: 11-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MASIMO CORP.
E AND LNOP SERIES OF SENSORS AND CABLES
ATTN: JAMES J CRONIN
2852 KELVIN AVE.
IRVINE, CA 92614-5826
510(k) NO: K013792
PHONE NO : 949-250-9688
DEVICE: MODIFICATION TO MASIMO SET RADICAL PULSE OXIMETER WITH SATSHAR
SE DECISION MADE: 11-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MASTER & FRANK ENT. CO., LTD.
ATTN: JENNIFER REICH
3892 SOUTH AMERICA WEST TRAIL
FLAGSTAFF, AZ 86001
510(k) NO: K012186
PHONE NO : 928-773-9488
DEVICE: MASTER & FRANK SURGICAL GOWNS (STERILE)
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MATH RESOLUTIONS, LLC.
ATTN: WENDEL DEAN RENNER
5975 GALES LANE
COLUMBIA, MD 21045
510(k) NO: K011845
PHONE NO : 410-997-9578
DEVICE: MILLCOMP
SE DECISION MADE: 04-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MED GEN, INC.
E SHIELD COMFORTCARE MAGNETIC INSOLES AND AEGIS MICROBE
ATTN: THEDORE BARASH
7284 W. PALMETTO PK. RD.
BOCA RATON, FL 33433-3406
510(k) NO: K013244
PHONE NO : 561-750-1100
DEVICE: COMFORTCARE COMPRESSION SUPPORT WITIH MAGNETS AND AEGIS MICROB
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDAFOR, INC.
ATTN: PHILIP B JARVI
5201 EAST RIVER ROAD, # 312
MINNEAPOLIS, MN 55421-1035
510(k) NO: K013225
PHONE NO : 763-571-6300
DEVICE: INSTACLOT FOR OTC USE, TRAUMASSTAT FOR PRESCRIPTION USE
SE DECISION MADE: 26-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDICAL ANALYSIS SYSTEMS, INC.
, DADE LIPID CONTROL, LIQUID ASSAYED LIPID CONTROL, LEVEL
ATTN: PENNY M LAYMAN
5300 ADOLFO RD.
CAMARILLO, CA 93012
510(k) NO: K013734
PHONE NO : 805-987-7891
DEVICE: MAS LIPID CONTROL, LIQUID ASSAYED LIPID CONTROL, LEVEL 1 AND 2
SE DECISION MADE: 07-DEC-2001
510(k) STATEMENT

MEDICAL ANALYSIS SYSTEMS, INC.
ATTN: PENNY M LAYMAN
5300 ADOLFO RD.
CAMARILLO, CA 93012
510(k) NO: K013995
PHONE NO : 805-987-7891
DEVICE: MODIFICATION TO MAS CARDIOLMMUNE TL; DADE CARDIAC TL
SE DECISION MADE: 21-DEC-2001
510(k) STATEMENT

MEDICAL METRICS, INC.
ATTN: ANN TUNSTALL
4600 NORTH PARK AVE.
SUITE 100
CHEVY CHASE, MD 20815-4518

510(k) NO: K013098
PHONE NO : 301-652-6739

DEVICE: KIMAX REMOTE VIEWING STATION
SE DECISION MADE: 07-DEC-2001

510(k) STATEMENT

MEDICAL SCIENTIFIC, INC.
ATTN: PAUL NARDELLA
125 JOHN HANCOCK RD.
TAUNTON, MA 02780

510(k) NO: K011202
PHONE NO : 508-880-7313

DEVICE: MSI BIPOLAR SHEATH
SE DECISION MADE: 31-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDLINE INDUSTRIES, INC.
ATTN: ANDREA HAFERKAMP
ONE MEDLINE PL.
MUNDELEIN, IL 60060-4486

510(k) NO: K013761
PHONE NO : 847-837-2759

DEVICE: MEDLINE EXCEL RECLINCER WHEELCHAIR
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDRAD, INC.
ATTN: FRANK W PELC III
ONE MEDRAD DR.
INDIANOLA, PA 15051

510(k) NO: K013815
PHONE NO : 412-767-2400

DEVICE: MEDRAD QWIK-FIT SYRINGE
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC CARDIAC SURGICAL PRODUCT
ATTN: ROGER W BRINK
620 WATSON SW
GRAND RAPIDS, MI 49504-6393

510(k) NO: K013013
PHONE NO : 616-643-7337

DEVICE: MEDTRONIC DLP ARTERIAL CANNULA WITH 3D TIP - 22 FR.
SE DECISION MADE: 04-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC NEUROLOGICAL
ATTN: MONAYA LEE
800 53RD AVE., N.E.
P.O. BOX 1250
MINNEAPOLIS, MN 55421

510(k) NO: K013063
PHONE NO : 763-514-5068

DEVICE: GRIP LOCK ANCHOR, MODEL 411374
SE DECISION MADE: 11-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC NEUROSURGERY
ATTN: JANET MCAULEY
125 CREMONA DR.,
UNIVERSITY BUSINESS CENTER
GOLETA, CA 93117

510(k) NO: K013000
PHONE NO : 805-968-1546

DEVICE: MEDTRONIC INVISX BURR HOLE LOCK, MODEL 60520
SE DECISION MADE: 05-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC PHYSIO-CONTROL CORP.
ATTN: SHERRI L POCOCK
11811 WILLOWS RD NE BX 97006
REDMOND, WA 98073-9706

510(k) NO: K011144
PHONE NO : 425-867-4332

DEVICE: LIFEPAK 600 AUTOMATED EXTERNAL DEFIBRILLATOR
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK, INC.
ATTN: RICHARD TREHARNE
1800 PYRAMID PL.
MEMPHIS, TN 38132

510(k) NO: K011406
PHONE NO : 901-396-3133

DEVICE: SPINAL MESH SYSTEM
SE DECISION MADE: 27-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK, INC.
ATTN: RICHARD W TREHARNE
1800 PYRAMID PL.
MEMPHIS, TN 38132

510(k) NO: K013663
PHONE NO : 901-396-3133

DEVICE: CEMENT RESTRICTOR
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC SOFAMOR DANEK, INC.
TEM
ATTN: RICK W TREHARNE
1800 PYRAMID PLACE
MEMPHIS, TN 38132

510(k) NO: K013829

PHONE NO : 901-396-3133

DEVICE: MODIFICATION TO TOWNLEY TRANSFACETPEDICULAR SCREW FIXATION SYS

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

MEDTRONIC SOFAMOR DANEK, INC.
ATTN: RICHARD TREHARNE
1800 PYRAMID PL.
MEMPHIS, TN 38132

510(k) NO: K014076
PHONE NO : 901-396-3133

DEVICE: MODIFICATION TO TSRH SPINAL SYSTEM
SE DECISION MADE: 27-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MENTOR CORP.
ATTN: DONNA CRAWFORD
201 MENTOR DRIVE
SANTA BARBARA, CA 93111

510(k) NO: K011500
PHONE NO : 805-879-6304

DEVICE: MENTOR CONTOUR PROFILE TISSUE EXPANDER
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MERITS HEALTH PRODUCTS CO., LTD.
ATTN: WINSTON ANDERSON
P.O. BOX 150356
CAPE CORAL, FL 33915

510(k) NO: K013788
PHONE NO : 800-963-7487

DEVICE: TRAVEL EASE ELECTRIC SCOOTER, MODEL PIONEER 5
SE DECISION MADE: 11-DEC-2001
510(k) STATEMENT

METALOR TECHNOLOGIES USA
ATTN: BRUCE BARTON
255 JOHN L. DIETSCH BLVD.
NORTH ATTLEBOROUGH, MA 02761

510(k) NO: K013505
PHONE NO : 800-554-5504

DEVICE: AUROFLUID PLUS
SE DECISION MADE: 19-DEC-2001
510(k) STATEMENT

MINDWAYS SOFTWARE, INC.
ATTN: CHRISTOPHER CANN
282 SECOND ST., 4TH FL.
SAN FRANCISCO, CA 94105-3130

510(k) NO: K002113
PHONE NO : 415-247-9930

DEVICE: CIXA HIP; CIXA; QCT PRO CIXA HIP
SE DECISION MADE: 04-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MINRAD, INC.
ATTN: HOWARD M HOLSTEIN
555 THIRTEENTH ST., NW
WASHINGTON, DC 20004-1109

510(k) NO: K013040
PHONE NO : 202-637-5600

DEVICE: LIGHT SABER INTRODUCER NEEDLE
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

MOJCA VALIJAVEC
ER SYSTEM
ATTN: MOJCA VALJAVEC
FOTONA D.D
STEGNE 7
LJUBLIJANA,

510(k) NO: K013047

PHONE NO :

DEVICE: FOTONA DUALIS ND:YAG LASER SYSTEM, FOTONA TWINLIGHT ND:YAG LAS

SE DECISION MADE: 06-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

NASTECH PHARMACEUTICAL COMPANY, IN510(k) NO: K012088
ATTN: PETER C APRILE PHONE NO : 631-273-0101
45 ADAMS AVE.
HAUPPAUGE, NY 11788-3605
DEVICE: NASTECH MAMMARY ASPIRATION SPECIMAN CYTOLOGY TEST MASCT
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

NEO METRICS, INC. 510(k) NO: K013024
ATTN: GENE CHAMPEAU PHONE NO : 763-559-4440
15301 HIGHWAY 55 WEST
MINNEAPOLIS, MN 55447
DEVICE: SELECTIVA GUIDEWIRE
SE DECISION MADE: 04-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

NICHOLS INSTITUTE DIAGNOSTICS 510(k) NO: K013992
MONE (1-84) IMMUNOASSAY
ATTN: ROBERT SCHMIDT PHONE NO : 949-240-5417
33051 CALLE AVIADOR
SAN JUAN CAPISTRANO, CA 92675
DEVICE: NICHOLS ADVANTAGE CHEMILUMINESCENCE BIO-INTACT PARATHYROID HOR
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

NICOLET VASCULAR, INC. 510(k) NO: K013419
ATTN: DAVID W WAGNER PHONE NO : 303-431-9400
6355 JOYCE DR.
GOLDEN, CO 80403
DEVICE: NICOLET ELECTROMAGNETIC NAVIGATION SYSTEM
SE DECISION MADE: 20-DEC-2001
510(k) STATEMENT

NIPRO MEDICAL CORP. 510(k) NO: K013287
ATTN: KAELYN B HADLEY PHONE NO : 859-224-8256
1384 COPPERFIELD COURT
LEXINGTON, KY 40514
DEVICE: NIPRO SAFELET CATH
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

NIPRO MEDICAL CORP. 510(k) NO: K013293
ATTN: KAELYN B HADLEY PHONE NO : 859-224-8256
1384 COPPERFIELD COURT
LEXINGTON, KY 40514
DEVICE: NIPRO HYPODERMIC NEEDLE
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

NOMOS CORP. 510(k) NO: K013036
ATTN: FRANCIS X DOBSCHA PHONE NO : 724-934-8242
2591 WEXFORD BAYNE RD., #400
SEWICKLEY, PA 15143
DEVICE: NOMOS MOTORIZED CRANE II
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

NORMATEC, INC. 510(k) NO: K013436
ATTN: JONATHAN S KAHAN PHONE NO : 202-637-5794
555 THIRTEENTH STREET
WASHINGTON, DC
DEVICE: NORMATEC PCD
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

OCULAR SCIENCES PUERTO RICO, INC. 510(k) NO: K013377
ENS
ATTN: RICHARD LIPPMAN PHONE NO : 301-770-9590
12300 TWINBROOK PARKWAY
SUITE 625
ROCKVILLE, MD 20852
DEVICE: BIOMEDICS UV COLORS (OCUFILCON D) SOFT (HYDROPHILIC) CONTACT L
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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| ODIN MEDICAL TECHNOLOGIES LTD.<br>ATTN: ADI ICKOWICZ<br>P.O. BOX 248<br>YOKNEAM ELIT, | 510(k) NO: K010850<br>PHONE NO : 972 495 91010 | DEVICE: POLESTAR N-10<br>SE DECISION MADE: 17-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| OHMEDA MEDICAL<br>ATTN: ALBERTO F PROFUMO<br>8880 GORMAN RD.<br>LAUREL, MD 20723 | 510(k) NO: K010388<br>PHONE NO : 410-888-5204 | DEVICE: SONDREX P.A.L. SYSTEM<br>SE DECISION MADE: 11-DEC-2001<br>510(k) STATEMENT |
| OLYMPUS AMERICA, INC.<br>ATTN: LAURA STORMS-TYLER<br>2 CORPORATE CENTER DR.<br>MELVILLE, NY 11747-3157 | 510(k) NO: K013066<br>PHONE NO : 631-844-5688 | DEVICE: HX-5/6-1 ENDOSCOPIC CLIPPING DEVICE<br>SE DECISION MADE: 11-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| OLYMPUS OPTICAL CO., LTD.<br>EQUIPMENT<br>ATTN: LAURA STORMS-TYLER<br>TWO CORPORATE CENTER DRIVE<br>MELVILLE, NY 11747-3157 | 510(k) NO: K013591<br><br>PHONE NO : 631-844-5688 | DEVICE: XENF-TP RHINO-LARYNGOFIBERSCOPE, ITS ACESSORIES AND ANCILLARY<br><br>SE DECISION MADE: 26-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| OPTICAL DIAGNOSTICS, INC.<br>ATTN: JOYCE DE WIT<br>490 MT. FURY CIRCLE SW<br>ISSAQUAH, WA 98027 | 510(k) NO: K013110<br>PHONE NO : 425-391-9259 | DEVICE: ANISEIKONIA INSPECTOR<br>SE DECISION MADE: 19-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| ORTHO-CLINICAL DIAGNOSTICS<br>ATTN: MARLENE A SHULMAN<br>100 INDIGO CREEK DRIVE<br>ROCHESTER, NY 14626-5101 | 510(k) NO: K013900<br>PHONE NO : 716-453-4041 | DEVICE: VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12 RANGE VERIFIERS<br>SE DECISION MADE: 21-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| ORTHOPEDIC SOURCE INC.<br>ATTN: STEVEN L MANDELL<br>PO BOX 307<br>LOOMIS, CA 95650 | 510(k) NO: K011887<br>PHONE NO : 800-500-0381 | DEVICE: AVALON CUP SYSTEM<br>SE DECISION MADE: 27-DEC-2001<br>510(k) STATEMENT |
| ORTHOSONIX, INC.<br>ATTN: RUSSELL PAGANO<br>615 7TH STREET NE<br>1ST FLOOR<br>WASHINGTON, DC 20002 | 510(k) NO: K013094<br>PHONE NO : 202-546-1266 | DEVICE: ORTHOSONIX ENERGEX<br>SE DECISION MADE: 14-DEC-2001<br><br>510(k) SUMMARY AVAILABLE FROM FDA |
| OSTEOIMPLANT TECHNOLOGY, INC.<br>ATTN: SAM SON<br>11201 PEPPER RD.<br>HUNT VALLEY, MD 21031-1201 | 510(k) NO: K012762<br>PHONE NO : 410-785-0700 | DEVICE: MJS POSTERIOR STABILIZED KNEE SYSTEM<br>SE DECISION MADE: 11-DEC-2001<br>510(k) STATEMENT |

OTSUKA PHARMACEUTICAL CO., LTD.
ATTN: CYNTHIA A SINCLAIR
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760

510(k) NO: K013371
PHONE NO : 508-643-0434

DEVICE: UBIT-IR300 INFRARED SPECTROMETRY SYSTEM
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

OXOID, LTD.
ATTN: ANDY HOLLINGSWORTH
WADE ROAD
BASINGSTOKE,HANTS,

510(k) NO: K012588
PHONE NO : 441 125 6841144

DEVICE: OXOID PYLORI TEST KIT, MODEL DR0130M
SE DECISION MADE: 10-DEC-2001
510(k) STATEMENT

PALOMAR MEDICAL PRODUCTS, INC.
ATTN: MARCY MOORE
131 KELEKENT LANE
CARY, NC 27511

510(k) NO: K013028
PHONE NO : 919-363-2432

DEVICE: PALOMAR SLP 1000
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PERCLOSE, INC.
ATTN: PATTY HEVEY
400 SAGINAW
REDWOOD CITY, CA 94063

510(k) NO: K013683
PHONE NO : 650-474-3202

DEVICE: MODIFICATION TO: ABBOTT VASCULAR SUTURE ANASTOMOSIS DEVICE
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHAMATECH INC.
ATTN: CARL MONGIOVI
9530 PADGETT ST., #101-106
SAN DIEGO, CA 92126

510(k) NO: K013407
PHONE NO : 858-635-5840

DEVICE: AT HOME DRUG TEST, MODEL 9084
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHAMATECH INC.
ATTN: CARL MONGIOVI
9530 PADGETT ST., #101
SAN DIEGO, CA 92126

510(k) NO: K013408
PHONE NO : 858-635-5840

DEVICE: AT HOME DRUG TEST, MODEL 9079
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHAMATECH INC.
ATTN: CARL MONGIOVI
9530 PADGETT ST., #101
SAN DIEGO, CA 92126

510(k) NO: K013409
PHONE NO : 858-635-5840

DEVICE: AT HOME DRUG TEST, MODEL 9074
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHAMATECH INC.
ATTN: CARL MONGIOVI
9530 PADGETT ST., #101
SAN DIEGO, CA 92126

510(k) NO: K013410
PHONE NO : 858-635-5840

DEVICE: AT HOME DRUG TEST, MODEL 9064
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHAMATECH INC.
ATTN: CARL MONGIOVI
9530 PADGETT ST., #101
SAN DIEGO, CA 92126

510(k) NO: K013412
PHONE NO : 858-635-5840

DEVICE: AT HOME DRUG TEST, MODEL 9069
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHILIPS MEDICAL SYSTEMS NORTH AMER
ATTN: PETER ALTMAN
472 WHEELERS FARMS ROAD
MILFORD, CT 06460

510(k) NO: K013344
PHONE NO : 203-926-7031

DEVICE: INTERA I/T
SE DECISION MADE: 11-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHILIPS MEDIZINSYSTEME BOEBLINGEN G510(k) NO: K013624
/V26 PATIENT MONITORS, BLOOD ANALYSIS PORTAL SYSTEM PLUG-I
ATTN: DENISE HALEY PHONE NO : 978-687-1501
3000 MINUTEMAN ROAD
ANDOVER, MA 01810

DEVICE: MODIFICATION TO AGILENT COMPONENT MONITORING SYSTEM (CMS), V24

SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PHOENIX DIAGNOSTICS, INC. 510(k) NO: K013451

ATTN: RAM NUNNA PHONE NO : 508-655-8310
8 TECH CIRCLE
NATICK, MA 01760

DEVICE: PHOENOIX ISE REAGENTS FOR ROCHE HITACHI, MODELS 700/900 SERIES

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

PLUS ORTHOPEDICS 510(k) NO: K013340
ATTN: HARTMUT LOCH PHONE NO : 888-741-7587
6055 LUSK BLVD.
SAN DIEGO, CA 92121-2700

DEVICE: RT-PLUS KNEE ADDITIONAL COMPONENTS
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

POLYMER TECHNOLOGY SYSTEMS, INC. 510(k) NO: K014099
ATTN: MARGO ENRIGHT PHONE NO : 317-870-5610
7736 ZIONSVILLE RD.
INDIANAPOLIS, IN 46268

DEVICE: BIOSCANNER PLUS
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

POREX SURGICAL, INC. 510(k) NO: K012108
ATTN: HOWARD MERCER PHONE NO : 678-479-1610
15 DART RD.
NEWNAN, GA 30265

DEVICE: MEDPOR COATED TEAR DRAIN
SE DECISION MADE: 19-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PORGES S.A. 510(k) NO: K013172
IP, DELINOTTE TIP, DUFOUR TIP, "OVER THE GUIDE" TIP, MODEL
ATTN: BERNARD ISMAEL PHONE NO : 331 460 13232
CENTRE D'AFFAIRES
LA BOURSIDIERE
LE PLESSIS ROBINSON CEDEX,

DEVICE: PORGES SILICONE PROSTATECTOMY CATHETER, STRAIGHT CYLINDRICAL T

SE DECISION MADE: 20-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

PRECISION BIOLOGIC 510(k) NO: K013708
ATTN: STEPHEN L DUFF PHONE NO : 902 468 6422
900 WINDMILL RD., SUITE 100
DARTMOUTH, N.S.,

DEVICE: REFERENCE CHECK, CATALOG NUMBER-RCN-10
SE DECISION MADE: 10-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

PULPDENT CORP. 510(k) NO: K013411
ATTN: KENNETH J BERK PHONE NO : 617-926-6666
80 OAKLAND ST.
P.O. BOX 780
WATERTOWN, MA 02471-0780

DEVICE: PULPDENT CAVITY PREPARATION IV
SE DECISION MADE: 12-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

PULSE METRIC, INC. 510(k) NO: K013358
ATTN: ROBERT DUFFY PHONE NO : 858-480-1171
11777 SORRENTO VALLEY ROAD
SAN DIEGO, CA 92121

DEVICE: DYNAPULSE 5000A MINI ABP BLOOD PRESSURE MONITORING SYSTEM
SE DECISION MADE: 13-DEC-2001
510(k) STATEMENT

RADI MEDICAL SYSTEMS AB
ODEL 12720
ATTN: MATS GRANLUND
PALMBLADSGATAN 10
UPPSALA,

510(k) NO: K013943
PHONE NO : 461 816 1000

DEVICE: RADIANALYZER, MODEL 12710, RADIVIEW (PC-SOFTWARE ACCESSORY), M
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

RADIOMED CORPORATION
ATTN: GORDON ROBERTS
ONE INDUSTRIAL WAY
TYNGSBORO, MA 01879-1400

510(k) NO: K013660
PHONE NO : 978-649-0300

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

RADIONICS, A DIVISION OF TYCO HEAL
ATTN: KEVIN J O'CONNELL
22 TERRY AVE.
BURLINGTON, MA 01803

510(k) NO: K013661
PHONE NO : 781-272-1233

DEVICE: XPLAN 2.2 WITH THE BODY SYSTEM
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

RANDOX LABORATORIES, LTD.
ATTN: P. ARMSTRONG
55 DIAMOND RD.
CRUMLIN, CO. ANTRIM,

510(k) NO: K011393
PHONE NO : 44 289 4422413

DEVICE: RANDOX PHENYTOIN
SE DECISION MADE: 04-DEC-2001
510(k) STATEMENT

REMINGTON PRODUCTS COMPANY, L.L.C.
ATTN: PAMELA J FURMAN
1400 SIXTEENTH ST. N.W.
SUITE 400
WASHINGTON, DC 20036

510(k) NO: K013328
PHONE NO : 202-789-1212

DEVICE: REMINGTON PARAFFIN SPA, MODELS HS-200. PFS-600
SE DECISION MADE: 03-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

RENNELS MEDICAL CORP.
ATTN: DAVID LEE
PO BOX 3626
MORGANTON, NC 28680-3626

510(k) NO: K013200
PHONE NO : 828-437-1085

DEVICE: RENMED CONTAMI-SHIELD BREATHING CIRCUIT SLEEVE, MODEL 9999/01
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

RESPIRONICS HEALTHSCAN, INC.
ATTN: SUSAN D GOLDSTEIN-FALK
55 NORTHERN BLVD.,
SUITE 200
GREAT NECK, NY 11021

510(k) NO: K013027
PHONE NO : 516-482-9001

DEVICE: MISTER NEB NEBULIZER COMPRESSOR, WITH NEBULIZER, MODEL HS123
SE DECISION MADE: 06-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012323
PHONE NO : 724-733-5866

DEVICE: BIPAP SYNCHRONY VENTILATORY SUPPORT SYSTEM
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

RESPONSE BIOMEDICAL CORP.
ATTN: WILLIAM J RADVAK
8855 NORTHBROOK COURT
BURNABY, BRITISH COLUMBIA,

510(k) NO: K012040
PHONE NO : 604 681 4101

DEVICE: RAMP MYOGLOBIN ASSAY
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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| REYNOLDS MEDICAL LTD.<br>ATTN: GEORGE MYERS<br>377 RT. 17 S.<br>HASBROUCK HEIGHTS, NJ 07604 | 510(k) NO: K013367<br>PHONE NO : 201-727-1703 | DEVICE: CARDIOCOLLECT PORTABLE ELECTROCARDIOGRAPH<br>SE DECISION MADE: 13-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| RILEY MEDICAL, INC.<br>ATTN: MARY MCNAMARA-CULLINANE<br>49 PLAIN STREET<br>NORTH ATTLEBORO, MA 02760 | 510(k) NO: K993535<br>PHONE NO : 508-643-0434 | DEVICE: METAPAK MULTI-PURPOSE INSTRUMENT TRAY<br>SE DECISION MADE: 07-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| ROCHE DIAGNOSTICS CORP.<br>ATTN: MIKE FLIS<br>9115 HAGUE ROAD<br>P.O. BOX 50457<br>INDIANAPOLIS, IN 46250-0457 | 510(k) NO: K012324<br>PHONE NO : 800-428-5074 | DEVICE: ACCU-CHEK ACTIVE TEST SYSTEM<br>SE DECISION MADE: 05-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| ROCHE DIAGNOSTICS CORP.<br>ATTN: KERWIN KAUFMAN<br>9115 HAGUE RD.<br>INDIANAPOLIS, IN 46250 | 510(k) NO: K013482<br>PHONE NO : 317-521-7637 | DEVICE: ABUSCREEN ONLINE OPIATES 300 / 2000<br>SE DECISION MADE: 21-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SA SCIENTIFIC, INC.<br>ATTN: RICARDO R MARTINEZ<br>4919 GOLDEN QUAIL<br>SAN ANTONIO, TX 78240 | 510(k) NO: K013379<br>PHONE NO : 210-699-8800 | DEVICE: SAS SIREPALERT<br>SE DECISION MADE: 12-DEC-2001<br>510(k) STATEMENT |
| SAFETY SYRINGES, INC.<br>ATTN: THOMAS L HALL<br>1939 PALOMAR OAKS WAY, SUITE A<br>CARLSBAD, CA 92009 | 510(k) NO: K013801<br>PHONE NO : 760-918-9908 | DEVICE: ULTRASAFE DENTAL INJECTION SYSTEM<br>SE DECISION MADE: 13-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SALIMETRICS LLC.<br>102<br>ATTN: EVE SCHWARTZ<br>101 INNOVATION BLVD.<br>SUITE 302<br>STATE COLLEGE, PA 16803 | 510(k) NO: K011323<br>PHONE NO : 814-234-7748 | DEVICE: HIGH SENSITIVITY CORTISOL ENZYME IMMUNOASSAY, MODEL 1-0101/1-0<br>SE DECISION MADE: 17-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SANYO NORTH AMERICA CORP.<br>IC,AND MCO-175M<br>ATTN: SACHI KATAOKA<br>900 N. ARLINGTON HEIGHTS RD<br>SUITE 310<br>TASCA, IL 60143-2844 | 510(k) NO: K013703<br>PHONE NO : 630-875-3536 | DEVICE: SANYO CO2 INCUBATORS, MODELS NOS. MCO-17AC, MCO-17AIC, MCO-20A<br>SE DECISION MADE: 14-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SAUFLON PHARMACEUTICALS, LTD.<br>ATTN: LIGIA DELACRUZ<br>49-53 YORK ST.<br>TWICKENHAM, MIDDLESEX, | 510(k) NO: K010559<br>PHONE NO : 440 208 3224200 | DEVICE: SAUFLON MULTI LENS CARE SYSTEM<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |

SAUFLON PHARMACEUTICALS, LTD.
ATTN: LIGIA DELACRUZ
49-53 YORK ST.
TWICKENHAM, MIDDLESEX,

510(k) NO: K013649
PHONE NO : 442 083 224200

DEVICE: SAUFLON 55 UV SOFT (HYDROPHILIC) CONTACT LENS
SE DECISION MADE: 26-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SGMP CO., LTD.
OE VERA AND VITAMIN E
ATTN: JANNA TUCKER
198 AVENUE DE LA D'EMERALD
SPARKS, NV 89434

510(k) NO: K013288

PHONE NO : 775-342-2612

DEVICE: NON-STERILE POWDER FREE GREEN LATEX EXAMINATION GLOVES WITH AL

SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SHANTOU INSTITUTE OF ULTRASONIC IN
ATTN: BOB LEIKER
1106 CHILTERN DRIVE
WALNUT CREEK, CA 94596

510(k) NO: K013327
PHONE NO : 925-556-1619

DEVICE: CTS-415
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIEMENS ELEMA AB
ATTN: DIANE WURZBURGER
MEDICAL SOLUTIONS
186 WOOD AVENUE SOUTH
ISELIN, NJ 08830-2770

510(k) NO: K010925
PHONE NO : 732-321-4765

DEVICE: SERVOI VENTILATOR SYSTEM, MODEL 64 87 800 E407E
SE DECISION MADE: 18-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

SIEMENS MEDICAL SYSTEMS, INC.
ATTN: JAMIE YIEH
186 WOOD AVENUE SOUTH
ISELIN, NJ 08830

510(k) NO: K013586
PHONE NO : 732-321-4625

DEVICE: MAGNETOM TRIO SYSTEM
SE DECISION MADE: 28-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIGMA DIAGNOSTICS, INC.
ATTN: WILLIAM R GILBERT II
545 SOUTH EWING AVE.
ST. LOUIS, MO 63103

510(k) NO: K013549
PHONE NO : 314-286-6693

DEVICE: SIGMA DIAGNOSTICS AUTO D-DIMER CALIBRATOR, MODEL A7971
SE DECISION MADE: 26-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIMS LEVEL 1, INC.
ATTN: GABRIEL J MURACA, JR.
160 WEYMOUTH ST.
ROCKLAND, MA 02370

510(k) NO: K011907
PHONE NO : 781-878-8011

DEVICE: SNUGGLE WARM 4000 CONVECTIVE WARMING SYSTEM
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SINCLAIR PHARMACEUTICALS, LTD.
ATTN: PRISCILLA COX
1 ALDER BROOK
CHINLEY, HIGH PEAK,

510(k) NO: K013056
PHONE NO : 44 166 3750410

DEVICE: GELCLAIR CONCENTRATED ORAL GEL
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SIRONA DENTAL SYSTEMS GMBH
ATTN: SHEILA M HEMEON-HEYER
49 PLAIN STREET
NORTH ATTLEBORO, MA 02760-4153

510(k) NO: K013650
PHONE NO : 508-643-0434

DEVICE: ORTHOPHOS DS/DC CEPH, ORTHOPHOS 5/PLUS/CD
SE DECISION MADE: 06-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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|---|---|---|
| SIRONA DENTAL SYSTEMS GMBH<br>ATTN: SHEILA HEMEON-HEYER<br>49 PLAIN STREET<br>NORTH ATTLEBORO, MA 02760-4153 | 510(k) NO: K013659<br>PHONE NO : 508-643-0434 | DEVICE: MODIFICATION TO SIDEXIS DIGITAL RADIOGRAPHY IMAGING SYSTEM<br>SE DECISION MADE: 06-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SMART GLOVE CORP. SDN BHD<br>ESS THAN 50 UG/G<br>ATTN: NG YEW SOON<br>LOT 6487 BATU 5 3/4<br>JALAN KAPAR<br>KLANG SELANGOR, | 510(k) NO: K013727<br><br>PHONE NO : 603 329 16100 | DEVICE: STERILE POWDER FREE LATEX SURGICAL GLOVES WITH PROTEIN CLAIM L<br><br>SE DECISION MADE: 07-DEC-2001<br><br>510(k) STATEMENT |
| SMITH & NEPHEW, INC.<br>ATTN: DAVID HENLEY<br>1450 E. BROOKS ROAD<br>MEMPHIS, TN 38116 | 510(k) NO: K012378<br>PHONE NO : 901-399-6487 | DEVICE: 3D HUMERAL HEADS<br>SE DECISION MADE: 13-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SMITH & NEPHEW, INC.<br>ONENIS<br>ATTN: DAVID HENLEY<br>1450 E. BROOKS ROAD<br>MEMPHIS, TN 38116 | 510(k) NO: K013658<br><br>PHONE NO : 901-399-6487 | DEVICE: MODIFICATION TO REFLECTION CROSS-LINKED UHMWPE ACETABULAR COMP<br><br>SE DECISION MADE: 05-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SMITH & NEPHEW, INC.<br>ATTN: JANET JOHNSON GREEN<br>1450 E. BROOKS ROAD<br>MEMPHIS, TN 38116 | 510(k) NO: K013989<br>PHONE NO : 901-399-5153 | DEVICE: ZIRCONIA CERAMIC FEMORAL HEAD - 12/14 TAPER<br>SE DECISION MADE: 19-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SOL WEISS MD INC<br>ATTN: SOL WEISS<br>7012 RESEDA BOULEVARD<br>SUITE A<br>RESEDA, CA 91335 | 510(k) NO: K013817<br>PHONE NO : 818-346-1515 | DEVICE: GLO-SPEC<br>SE DECISION MADE: 21-DEC-2001<br><br>510(k) SUMMARY AVAILABLE FROM FDA |
| SONOSITE,INC.<br>ATTN: MICHAEL HOFFMAN<br>21919 30TH DRIVE SE.<br>BOTHELL, WA 98021-3904 | 510(k) NO: K014116<br>PHONE NO : 425-951-1297 | DEVICE: HAND-CARRIED ULTRASOUND SYSTEM<br>SE DECISION MADE: 20-DEC-2001<br>510(k) SUMMARY AVAILABLE FROM FDA |
| SOPRO<br>ATTN: PIERRE MONTILLOT<br>PLACE ST. CHRISTOPHE<br>LES ACCATES-LA VALENTINE<br>MARSEILLE, | 510(k) NO: K013090<br>PHONE NO : 334 912 70727 | DEVICE: SOPRO 67D OPERATING ROOM CAMERA<br>SE DECISION MADE: 13-DEC-2001<br><br>510(k) STATEMENT |
| STANDARD TEXTILE CO., INC.<br>ATTN: BRADLEY J BUSHMAN<br>ONE KNOLLCREST DR.<br>P.O. BOX 371805<br>CINCINNATI, OH 45237-1600 | 510(k) NO: K012268<br>PHONE NO : 513-761-9255 | DEVICE: TRIMAX<br>SE DECISION MADE: 03-DEC-2001<br><br>510(k) SUMMARY AVAILABLE FROM FDA |

STELLARTECH RESEARCH CORP.
ATTN: JAMES R SANTOS
1346 BORDEAUX DR.
SUNNYVALE, CA 94089
510(k) NO: K013139
PHONE NO : 408-331-3000
DEVICE: STELLARTECH COAGULATION SYSTEM
SE DECISION MADE: 18-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

STENTOR, INC.
ATTN: GARY J ALLSEBROOK
16303 PANORAMIC WAY
SAN LEANDRO, CA 94578
510(k) NO: K013630
PHONE NO : 510-276-2648
DEVICE: ISITE RADIOLOGY
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

STERIS CORP.
ATTN: ROBERT H MCCALL
2720 GUNTER PARK DRIVE EAST
MONTGOMERY, AL 36109
510(k) NO: K013242
PHONE NO : 334-213-3150
DEVICE: AMSCO HARMONY SURGICAL LIGHTING AND MEDIA SYSTEM
SE DECISION MADE: 13-DEC-2001
510(k) STATEMENT

STERLING MEDIVATIONS, INC.
ATTN: JOEL DOUGLAS
25285 LA LOMA DR.
LOS ALTOS HILLS, CA 94022-4583
510(k) NO: K013502
PHONE NO : 650-949-0470
DEVICE: SIMPLICITY CLASSIC WING QD INFUSION SET
SE DECISION MADE: 03-DEC-2001
510(k) STATEMENT

STERLING MEDIVATIONS, INC.
UDING INSULIN, FROM AN EXTERNAL INFUSION PUMP
ATTN: JOEL DOUGLAS
25285 LA LOMA DR.
LOS ALTOS HILLS, CA 94022-4583
510(k) NO: K013767
PHONE NO : 650-814-4083
DEVICE: SIMPLICITY INFUSION RESERVOIR FOR USE TO INFUSE MEDICINE, INCL
SE DECISION MADE: 12-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

STRYKER CORP.
ATTN: NICOLE PETTY
4100 E. MILHAM AVENUE
KALAMAZOO, MI 49001
510(k) NO: K014091
PHONE NO : 616-323-7700
DEVICE: STRYKER PAINPUMP
SE DECISION MADE: 31-DEC-2001
510(k) STATEMENT

STRYKER LEIBINGER
Y SYSTEM,VIRTUAL FLUOROSCOPY
ATTN: ROBIN L ROWE
4100 EAST MILHAM AVE
KALAMAZOO, MI 49001
510(k) NO: K012380
PHONE NO : 616-323-7700
DEVICE: MODIFICATION TO: STRYKER NAVIGATION SYSTEM, STRYKER FLUOROSCOP
SE DECISION MADE: 03-DEC-2001
510(k) STATEMENT

SULZER ORTHOPEDICS, INC.
ATTN: FRANCES E HARRISON
9900 SPECTRUM DR.
AUSTIN, TX 78717
510(k) NO: K013031
PHONE NO : 512-432-9306
DEVICE: MOST OPTIONS SYSTEM
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SULZER ORTHOPEDICS, INC.
ATTN: MITCHELL A DHORITY
9900 SPECTRUM DRIVE
AUSTIN, TX 78717
510(k) NO: K013935
PHONE NO : 512-432-9202
DEVICE: ALLOFIT ACETABULAR SYSTEM 32MM ALPHA DURASUL INSERTS
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SURGICAL IMPLANT GENERATION NETWOR
ATTN: DOUG DONNELLY
2950 GEORGE WASHINGTON WAY
RICHLAND, WA 99352-1615

510(k) NO: K013132
PHONE NO : 509-371-1107

DEVICE: SIGN IM NAIL
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

SURGIN INC
ATTN: DON HAAR
14762 BENTLEY CIRCLE
TUSTIN, CA 92780

510(k) NO: K013337
PHONE NO : 714-832-6300

DEVICE: PRIZM KERATOME BLADE (NIDEK MODEL), MODEL MK8514NI
SE DECISION MADE: 13-DEC-2001
510(k) STATEMENT

SYNAPSYS, INC.
ATTN: JULIEN CHAUSSY
150-10 132 AVENUE
JAMAICA, NY 11434

510(k) NO: K012415
PHONE NO : 718-525-3376

DEVICE: AURIS AEP
SE DECISION MADE: 18-DEC-2001
510(k) STATEMENT

SYNTHES (USA)
ATTN: ANGELA J SILVESTRI
1690 RUSSELL RD.
PAOLI, PA 19301

510(k) NO: K011897
PHONE NO : 610-647-9700

DEVICE: NORIAN SRS BONE VOID FILLER
SE DECISION MADE: 20-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K012945
PHONE NO : 610-647-9700

DEVICE: SYNTHES 2.4 MM CANNULATED SCREW
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013044
PHONE NO : 610-647-9700

DEVICE: SYNTHES 3.9 MM PELVIC SCREWS
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013248
PHONE NO : 610-647-9700

DEVICE: SYNTHES LCP DISTAL TIBIA PLATES
SE DECISION MADE: 19-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
SYSTEM
ATTN: BONNIE J SMITH
1690 RUSSELL RD.
PAOLI, PA 19301

510(k) NO: K013527

PHONE NO : 610-647-9700

DEVICE: MODIFICATION TO SYNTHES (USA) REAMER IRRIGATOR ASPIRATOR (RIA)

SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

TCI NEW YORK
ATTN: ERIKA B AMMIRATI
575 SHIRLYNN COURT
LOS ALTOS, CA 94022

510(k) NO: K013323
PHONE NO : 650-949-2768

DEVICE: TCI-31 LIFELONG OVULATION TESTER
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

TEKMEDIC (M) SDN BHD
ATTN: KOK-KEE HON
P.O. BOX 11112
ALEXANDRIA, VA 22312-9998
510(k) NO: K013317
PHONE NO : 703-941-7656
DEVICE: TEKMEDIC POWDER-FREE WITH PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS)
SE DECISION MADE: 17-DEC-2001
510(k) STATEMENT

TERUMO CARDIOVASCULAR SYSTEMS CORP
ATTN: GARRY A COURTNEY
125 BLUE BALL ROAD
ELKTON, MD 21921
510(k) NO: K010443
PHONE NO : 800-283-7866
DEVICE: CAPIOX SX10 HOLLOW FIBER OXYGENATOR WITH/WITHOUT HARDSHELL RESERVOIR WITH X-COATING
SE DECISION MADE: 11-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

TETRAD CORP.
ATTN: CHARLES F HOTTINGER
357 INVERNESS DR. SOUTH,
SUITE A
ENGLEWOOD, CO 80112
510(k) NO: K013849
PHONE NO : 408-741-1006
DEVICE: TETRAD MODEL TC-EC7-ACP, -L5-, -L7-, -V4-ACP TRANSDUCERS
SE DECISION MADE: 03-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

THERASENSE, INC.
ATTN: EVE A CONNER
1360 SOUTH LOOP ROAD
ALAMEDA, CA 94502-7000
510(k) NO: K012014
PHONE NO : 510-749-5400
DEVICE: MODIFICATION TO BLOOD GLUCOSE MONITORING SYSTEM
SE DECISION MADE: 05-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

TOSOH MEDICS, INC.
ATTN: LOIS NAKAYAMA
347 OYSTER POINT BLVD.,
SUITE 201
SOUTH SAN FRANCISCO, CA 94080
510(k) NO: K012820
PHONE NO : 650-615-4970
DEVICE: AIA-PACK CINI 2ND-GEN ASSAY
SE DECISION MADE: 14-DEC-2001
510(k) STATEMENT

TREK DIAGNOSTIC SYSTEMS, INC.
ATTN: CYNTHIA C KNAPP
29299 CLEMENS RD., SUITE 1-K
WESTLAKE, OH 44145
510(k) NO: K013580
PHONE NO : 800-216-9036
DEVICE: SENSITITRE HAEMOPHILUS/STREPTOCOCCUS PNEUMONIAE (HP) MIC SUSCEPTIBILITY PLATE
SE DECISION MADE: 12-DEC-2001
510(k) STATEMENT

TREK DIAGNOSTIC SYSTEMS, INC.
ATTN: CYNTHIA C KNAPP
29299 CLEMENS RD., SUITE 1-K
WESTLAKE, OH 44145
510(k) NO: K013925
PHONE NO : 800-216-9036
DEVICE: SENSITITRE HAEMOPHILUS/STREPTOCOCCUS PNEUMONIAE (HP) MIC SUSCEPTIBILITY PLATES
SE DECISION MADE: 21-DEC-2001
510(k) STATEMENT

TRIAD MEDICAL, INC.
ATTN: RITA GIEBEL
3722 AVE. SAUSALITO
IRVINE, CA 92606
510(k) NO: K013903
PHONE NO : 949-262-0411
DEVICE: HELICAL COMPRESSION ANCHOR SYSTEM, CANNULATED, VERSION 2
SE DECISION MADE: 17-DEC-2001
510(k) STATEMENT

TRIGG LABORATORIES, INC.
ATTN: W. PATRICK NOONAN
WARNER CENTER PLAZA
21800 OXNARD STREET, SUITE 840
WOODLAND HILLS, CA 91367

510(k) NO: K013086
PHONE NO : 818-887-5600

DEVICE: WET LIGHT PERSONAL MOISTURIZER
SE DECISION MADE: 13-DEC-2001

510(k) STATEMENT

TROPHY RADIOLOGIE
ATTN: MARIE-PIERRE LABAT-CAMY
4 RUE F. PELLOUTIER CROISSY
BEAUBOURG
MARNE LA VALLEE CEDEX 2,

510(k) NO: K012514
PHONE NO : 331 648 08500

DEVICE: DIGIPAN / DPI
SE DECISION MADE: 21-DEC-2001

510(k) STATEMENT

TYCO HEALTHCARE
ATTN: DAVID A OLSON
15 HAMPSHIRE STREET
MANSFIELD, MA 02048

510(k) NO: K013556
PHONE NO : 508-261-8000

DEVICE: MONOJECT PREFILL HEPARIN LOCK FLUSH SYRINGE
SE DECISION MADE: 31-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

UNION MEDICAL USA
ATTN: ANNIE VELEZ
3750 NW 114TH AVENUE
UNIT #5
MIAMI, FL 33178

510(k) NO: K012071
PHONE NO : 305-629-9339

DEVICE: ENT LASERVISION
SE DECISION MADE: 03-DEC-2001

510(k) STATEMENT

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

510(k) NO: K013860
PHONE NO : 203-845-1390

DEVICE: AUTO SUTURE SURGICAL STAPLES
SE DECISION MADE: 19-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

UNITED STATES SURGICAL, A DIVISION
ATTN: JENNIFER SCHUCK
150 GLOVER AVE.
NORWALK, CT 06856

510(k) NO: K013890
PHONE NO : 203-845-4512

DEVICE: SURGICAL DYNAMICS MENISCAL STAPLE
SE DECISION MADE: 11-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

USA INSTRUMENTS, INC.
ATTN: RONY THOMAS
1515 DANNER DRIVE
AURORA, OH 44202

510(k) NO: K011683
PHONE NO : 330-562-1000

DEVICE: NURVO 9000 ENDOCAVITARY COILS
SE DECISION MADE: 10-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

USA INSTRUMENTS, INC.
ATTN: RONY THOMAS
1515 DANNER DRIVE
AURORA, OH 44202

510(k) NO: K013528
PHONE NO : 330-562-1000

DEVICE: CRYSTAL 5000 PHASES ARRAY TMJ COIL
SE DECISION MADE: 13-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

USA INSTRUMENTS, INC.
ATTN: RONY THOMAS
1515 DANNER DRIVE
AURORA, OH 44202

510(k) NO: K013541
PHONE NO : 330-562-1000

DEVICE: SHOULDER COIL
SE DECISION MADE: 14-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K011832
PHONE NO : 863-683-8680

DEVICE: VANGUARD REPROCESSED FEMORAL COMPRESSION DEVICE
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

VASCUMETRIX, LLC
ATTN: MIKE HAMMONS
2824 N. POWER RD.
SUITE 113-278
MEAS, AZ 85215-1674

510(k) NO: K012256
PHONE NO : 480-807-6300

DEVICE: GELBISH VASCULAR DILATOR
SE DECISION MADE: 20-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

VENTLAB CORP.
ATTN: MARGE WALLS-WALKER
2934 HWY. 601 NORTH
MOCKSVILLE, NC 27028

510(k) NO: K013308
PHONE NO : 336-492-2636

DEVICE: VENTLAB HYPERINFLATION BAG SYSTEM
SE DECISION MADE: 20-DEC-2001
510(k) STATEMENT

VERTIS NEUROSCIENCE, INC.
00, SGXXX
ATTN: LORI GLASTETTER
2101 FOURTH AVE STE 200
SEATTLE, WA 98121-2329

510(k) NO: K011702

PHONE NO : 206-902-1902

DEVICE: VERTIS PNT CONTROL UNIT, VERTIS PNT SAFEGUIDE KIDS, MODELS CU1

SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

VIATRONIX, INC.
ATTN: SUSAN D GOLDSTEIN-FALK
55 NORTHERN BLVD.
SUITE 200
GREAT NECK, NY 11021

510(k) NO: K013146
PHONE NO : 516-482-9001

DEVICE: VIATRONIC V3D CALCIUM SCORING
SE DECISION MADE: 07-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

VICTORCH MEDITEK, INC.
ATTN: PIERCE LIU
7313 CARROLL RD., SUITE A-B
SAN DIEGO, CA 92121

510(k) NO: K013678
PHONE NO : 858-530-9191

DEVICE: VICTORCH MEDITEK'S HCG TEST CARD
SE DECISION MADE: 27-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

VICTORCH MEDITEK, INC.
ATTN: PIERCE LIU
7313 CARROLL RD., SUITE A-B
SAN DIEGO, CA 92121

510(k) NO: K013702
PHONE NO : 858-530-9191

DEVICE: VICTORCH HCG TEST STRIP
SE DECISION MADE: 27-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

VIDAMED, INC.
ATTN: YI CHEN
46107 LANDING PKWY.
FREMONT, CA 94538

510(k) NO: K012587
REUSABLE HANDLE, DISOISABLE HANDPIECE REUSABLE TELESCOPE
PHONE NO : 510-492-4934

DEVICE: RF GENERATORS, DISPOSABLE CARTRIDGE KIT, DISPOSABLE CARTRIDGE,

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

W. L. GORE & ASSOCIATES, INC.
ATTN: R. LARRY PRATT
3450 WEST KLINE LANE
P.O. BOX 500
FLAGSTAFF, AZ 86002-0500

510(k) NO: K013282
PHONE NO : 928-779-2771

DEVICE: GORE INTRODUCER SHEATH
SE DECISION MADE: 14-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

W.L. GORE & ASSOCIATES,INC
ATTN: JACQUELINE KALBACH
3450 KILTIE LANE
P.O. BOX 500
FLAGSTAFF, AZ 86002-0500

510(k) NO: K013346
PHONE NO : 928-864-3731

DEVICE: GORE DRAPEABLE ST/LT REGENERATIVE MEMBRANE
SE DECISION MADE: 19-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

WIELAND EDELMETALLE GMBH & CO.
ATTN: GERHARD POLZER
SCHWENNINGER STRABE 13
D-75179 PFORZHEIM,

510(k) NO: K012839
PHONE NO : 49 723 13705219

DEVICE: AUROPAL, ORDER-NO.: 2101
SE DECISION MADE: 31-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

WIENER LABORATORIES S.A.I.C.
0106; 4 250 ML CAT. # 1400107; WIENER LAB. GILICEMIA ENZCA
ATTN: VIVIANA CETOLA
2944 RIOBAMBA
ROSARIO,

510(k) NO: K011953
PHONE NO : 543 414 329191

DEVICE: WIENER LAB. GLICEMIA ENZIMATICA AA MODELS 1 X 250 ML CAT. #140

SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013652
PHONE NO : 543 414 329191

DEVICE: WIENER LAB. CA-COLOR AA, MODEL 4 X 50 ML CAT.N 1152002
SE DECISION MADE: 21-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013035
PHONE NO : 901-867-4457

DEVICE: GUARDIAN LIMB SALVAGE SYSTEM
SE DECISION MADE: 07-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

WRP SPECIALTY PRODUCTS SDN. BHD.
CONTENT LABELING)
ATTN: MOHD H HUSSEIN
LOT11 JALAN2 PERUSAHAAN BANDAR
KAWASAN BARU SALAK TINGGI
SEPANG, SELANGOR,

510(k) NO: K013942
PHONE NO : 603 870 69788

DEVICE: POWDER FREE BLUE LATEX EXAMINATION GLOVE, NON-STERILE (PROTEIN

SE DECISION MADE: 31-DEC-2001

510(k) SUMMARY AVAILABLE FROM FDA

ZEUS SCIENTIFIC, INC.
ATTN: MARK J KOPNITSKY
P.O. BOX 38
RARITAN, NJ 08869

510(k) NO: K011244
PHONE NO : 908-526-3744

DEVICE: ZEUS SCIENTIFIC, INC. ATHENA MULTI-LYTE ANA TEST SYSTEM
SE DECISION MADE: 10-DEC-2001
510(k) STATEMENT

ZIMMER, INC.
R) ARTICULAR SURFACE COMPONENTS
ATTN: STEPHEN H MCKELVEY
P.O. BOX 708
WARSAW, IN 46581-0708

510(k) NO: K013991
PHONE NO : 219-372-4944

DEVICE: PROLONG HIGHLY CROSSLINKED POLYETHYLENE CRUCIATE RETAINING (C

SE DECISION MADE: 27-DEC-2001
510(k) SUMMARY AVAILABLE FROM FDA

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|---|---|
| TOTAL 510(k)s THIS PERIOD | 288 |
| TOTAL WITH SUMMARIES | 233 |
| TOTAL WITH STATEMENTS | 55 |