"O" CO., INC.
ATTN: DAVID D DALISE
600 PAISANO, N.E., SUITE A
ALBUQUERQUE, NM 87123

510(k) NO: K011524
PHONE NO : 800-228-0477

DEVICE: IMMEDIATE STABILIZING DEVICE (ISD)
SE DECISION MADE: 10-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

3M CO.
ATTN: JOANN L HUEHN
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55144-1000

510(k) NO: K020589
PHONE NO : 651-733-9209

DEVICE: 3M COMPLY 1228 GAS PLASMA INDICATOR TAPE
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020946
PHONE NO : 011 498 152700139

DEVICE: ADPER PROMPT
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

3M UNITEK
ATTN: MARLYN SCHEFF
2724 SOUTH PECK RD.
MONROVIA, CA 91016

510(k) NO: K020394
PHONE NO : 626-574-4496

DEVICE: APC PLUS ADHESIVE
SE DECISION MADE: 12-APR-2002
510(k) STATEMENT

AB BIODISK
ATTN: ANNE BOLMSTROM
DALVAGEN 10
SOLNA,

510(k) NO: K020748
PHONE NO : 468 730 0768

DEVICE: ETEST ERTAPENEM
SE DECISION MADE: 29-APR-2002
510(k) STATEMENT

ACCURAY, INC.
ATTN: DONALD E CADDES
570 DEL REY AVE.
SUNNYVALE, CA 94085

510(k) NO: K020294
PHONE NO : 408-522-3740

DEVICE: MOTION TRACKING
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ACIST MEDICAL SYSTEMS
ATTN: CARL M BEAURLINE
7450 FLYING CLOUDS DR.
SUITE 150
EDEN PRAIRIE, MN 55344

510(k) NO: K021015
PHONE NO : 612-995-9319

DEVICE: ACIST PLUS 4 ANGIOGRAPHIC CATHETER
SE DECISION MADE: 26-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

ACKRAD LABORATORIES
ODEL 61-5007
ATTN: RICHARD HETTENBACH
70 JACKSON DR.
CRANFORD, NJ 07016

510(k) NO: K020951

PHONE NO : 908-276-6390

DEVICE: H/S CATHETER SET (5F), MODEL 61-5005; H/S CATHETER SET (7F), M

SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ACKRAD LABORATORIES
PHERE PROCEDURE TRAY & MULTIPURPOSE PROCEDURE TRAY
ATTN: RICHARD HETTENBACH
70 JACKSON DR.
CRANFORD, NJ 07016

510(k) NO: K020954

PHONE NO : 908-276-6390

DEVICE: H/S PROCEDURE TRAY (5F), H/S PROCEDURE TRAY (7F), H/S ELLIPTOS

SE DECISION MADE: 24-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

945-0120

1ST 114

ADVANCED HEALTHCARE LTD. ATTN: PERRY KASHFIAN 13161 TELFAIR AVE. SYLMAR, CA 91342	510(k) NO: K020376 PHONE NO : 818-362-2600	DEVICE: AHL GENERIC GLASS IONOMER AESTHETIC RESTORATIVE SE DECISION MADE: 09-APR-2002 510(k) STATEMENT
ADVEN MEDICAL ATTN: MARK W ALDANA 1001 SLATON HWY. LUBBOCK, TX 79404	510(k) NO: K012699 PHONE NO : 806-745-7718	DEVICE: REPROCESSED USED DISPOSABLE BIOPSY FORCEPS SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: GEORG KELLER 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K013569 PHONE NO : 800-258-1946	DEVICE: ORTHOPILOT 2 SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AESCULAP, INC. ATTN: JOYCE KILROY 3773 CORPORATE PKWY. CENTER VALLEY, PA 18034	510(k) NO: K020728 PHONE NO : 800-258-1946	DEVICE: MIETHKE SHUNT SYSTEM SE DECISION MADE: 05-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
ALBA-WALDENSIAN, INC. ATTN: DAVID BOWMAN 425 NORTH GATEWAY AVE ROCKWOOD, TN 37854	510(k) NO: K020592 PHONE NO : 865-354-0410	DEVICE: ALBAHEALTH C.A.L.M. SLEEVE, MODEL 59001 SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AMERICAN DIAGNOSTICA, INC. ATTN: JOHN BERRYMAN 222 RAILROAD AVE. GREENWICH, CT 06830	510(k) NO: K013637 PHONE NO : 203-661-0000	DEVICE: ACTICHROME HEPARIN (ANTI-FIIA) SE DECISION MADE: 16-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
APEX DENTAL MATERIALS, INC. ATTN: CHRIS KULTON 603 BERKLEY COURT SCHAUMBURG, IL 60194	510(k) NO: K020570 PHONE NO : 847-490-1014	DEVICE: SIMPLICITY SE DECISION MADE: 24-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
APPLIED BIOTECH, INC. ATTN: STEVE WORCESTER 10237 FLANDERS CT. SAN DIEGO, CA 92121	510(k) NO: K021093 PHONE NO : 858-587-6771	DEVICE: CHECKCUP IMMUNOASSAY SYSTEM FOR DRUGS OF ABUSE SE DECISION MADE: 24-APR-2002 510(k) STATEMENT
APPLIED MEDICAL RESOURCES CORP. ATTN: ANIL BHALANI 22872 AVENIDA EMPRESSA RANCHO SANTA MARGARITA, CA 92688	510(k) NO: K020435 PHONE NO : 949-713-8327	DEVICE: WOUND PROTECTOR/RETRACTOR SE DECISION MADE: 15-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
AR ALLIANCE HEALTHCARE SDN. BHD. ATTN: CHAU CHOON CHUAN 8, LORONG INDUSTRI 11, KAWASAN PERINDUSTRIAN BUKIT PANCHOR, NIBONG TEBAL, PULAU PINANG,	510(k) NO: K020838 PHONE NO : 60 04 5937616	DEVICE: ULTRA TOUCH POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS) SE DECISION MADE: 23-APR-2002 510(k) STATEMENT

ARTEMIS MEDICAL, INC.
ATTN: ALLAN L ABATI
21021 CORSAIR BLVD.
HAYWARD, CA 94545
510(k) NO: K020024
PHONE NO : 510-259-3150
DEVICE: CARIS MINITOME BIOPSY INSTRUMENT
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ARTHREX, INC.
HREX BIO-TENODESIS SCREW, MODELS AR-1555B
ATTN: ANN WATERHOUSE
2885 SOUTH HORSESHOE DR.
NAPLES, FL 34104
510(k) NO: K020043
PHONE NO : 941-643-5553
DEVICE: 4.0 MM ARTHREX BIO-TENDOESIS SCREW, MODEL AR-1540B; 5.5 MM ARI
SE DECISION MADE: 02-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.
ORD, WANDS
ATTN: VALERIE DEFIESTA-NG
680 VAQUEROS AVE.
SUNNYVALE, CA 94085
510(k) NO: K020832
PHONE NO : 408-736-0224
DEVICE: ARTHROCARE CONTROLLER, ARTHROCARE CABLE, FOOT CONTROL, POWER C
SE DECISION MADE: 09-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ATRICURE, INC.
RHP1
ATTN: MARK L FRIEDMAN
6033 SCHUMACHER PARK DRIVE
WEST CHESTER, OHIO, OH 45069
510(k) NO: K020919
PHONE NO : 513-755-4105
DEVICE: ATRICURE BIPOLAR SYSTEM, MODELS ASU1, ASU2, ASU3, LHP1, LHP2,
SE DECISION MADE: 19-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ATRION MEDICAL PRODUCTS, INC.
ATTN: DAN CLARK
1426 CURT FRANCIS RD.
ARAB, AL 35016
510(k) NO: K020333
PHONE NO : 256-586-1580
DEVICE: ATRION MEDICAL QL FLUID DISPENSING SYRINGE
SE DECISION MADE: 25-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ATRIUM MEDICAL CORP.
ATTN: KAREN HALL
5 WENTWORTH DR.
HUDSON, NH 03051
510(k) NO: K020767
PHONE NO : 603-880-1433
DEVICE: ADVANTA SST BIFURCATED GRAFT
SE DECISION MADE: 03-APR-2002
510(k) STATEMENT

AZARY TECHNOLOGIES LLC.
ATTN: JOSEPH M AZARY
P.O. BOX 2156
HUNTINGTON, CT 06484
510(k) NO: K013672
PHONE NO : 203-944-9320
DEVICE: BRUGES DISTRACTION - ANCHORING - OSTEOSYNTHESIS SYSTEM
SE DECISION MADE: 08-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BARCO NV
ATTN: FRANK FERGUSON
P.O. BOX 12038
LA JOLLA, CA 92039-2038
510(k) NO: K020058
PHONE NO : 858-587-1147
DEVICE: MEDICAL LE
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BARCO NV
ATTN: FRANK FERGUSON
P.O. BOX 12038
LA JOLLA, CA 92039-2038
510(k) NO: K020059
PHONE NO : 858-587-1147
DEVICE: MFCD 118I
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BARCO NV ATTN: FRANK FERGUSON P.O. BOX 12038 LA JOLLA, CA 92039-2038	510(k) NO: K020061 PHONE NO : 858-587-1147	DEVICE: IMAGEDESK SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAUSCH & LOMB INCORPORATED ATTN: DEBRA L.B. KETCHUM 1400 N. GOODMAN STREET PO BOX 30450 ROCHESTER, NY 14603-0450	510(k) NO: K013762 PHONE NO : 716-338-8638	DEVICE: RIGID GAS PERMEABLE CONTACT LENS SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYER GROUP DIAGNOSTICS ATTN: GEORGE M TANCOS 1884 MILES AVENUE P.O. BOX 70 ELKHART, IN 46515-0070	510(k) NO: K020208 PHONE NO : 574-262-6928	DEVICE: GLUCOMETER ELITE DIABETES CARE SYSTEM (MODIFIED) SE DECISION MADE: 29-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYER GROUP DIAGNOSTICS ATTN: GEORGE M TANCOS 1884 MILES AVENUE P.O. BOX 70 ELKHART, IN 46515-0070	510(k) NO: K020210 PHONE NO : 574-262-6928	DEVICE: GLUCOMETER DEX BLOOD GLUCOSE SYSTEM (MODIFIED) SE DECISION MADE: 30-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BCI, INC. ATTN: DONALD ALEXANDER N7 W22025 JOHNSON ROAD WAUKESHA, WI 53186	510(k) NO: K020350 PHONE NO : 262-542-3100	DEVICE: BCI 3180 PULSE OXIMETER SE DECISION MADE: 30-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BECTON DICKINSON INFUSION THERAPY ATTN: LESLIE WOOD 9450 SOUTH STATE ST. SANDY, UT 84070	510(k) NO: K013621 PHONE NO : 801-565-2504	DEVICE: BD SAF-T PRN LUER ACTIVATED VALVE, MODEL 385100 SE DECISION MADE: 16-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BECTON, DICKINSON AND COMPANY ATTN: JODY J HOFFMANN 7 LOVETON CIR. SPARKS, MD 21152-0999	510(k) NO: K014123 PHONE NO : 410-316-4192	DEVICE: BACTEC MGIT 960 SIRE KITS SE DECISION MADE: 19-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BECTON, DICKINSON AND COMPANY ATTN: BRADFORD M SPRING 7 LOVETON CIR. SPARKS, MD 21152-0999	510(k) NO: K020323 PHONE NO : 410-316-4206	DEVICE: BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BEXLEY TRADING, INC. ATTN: MICHAEL ZMUDA 1105 BUCKBRUSH DR FOLSOM, CA 95630	510(k) NO: K003896 PHONE NO :	DEVICE: LYMPHA VISION-EXPERT SE DECISION MADE: 24-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD
ATTN: YVETTE LLOYD
9500 JERONIMO ROAD
IRVINE, CA 92618

510(k) NO: K020610
PHONE NO : 949-598-1200

DEVICE: LYPHOCHEK WHOLE BLOOD METALS CONTROL MODEL # 527, 528, 529
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD
ATTN: MARIA ZEBALLOS
9500 JERONIMO ROAD
IRVINE, CA 92618

510(k) NO: K020878
PHONE NO : 949-598-1367

DEVICE: LYPHOCHEK HEMOSTASIS, MODELS 798, 799
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIO-RAD LABORATORIES, INC.
ATTN: ELIZABETH PLATT
9500 JERONIMO ROAD
IRVINE, CA 92618-2017

510(k) NO: K020817
PHONE NO : 949-598-1200

DEVICE: LIQUICHEK URINE CHEMISTRY CONTROL
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOLITEC, INC.
ATTN: CAROL J MORELLO
515 SHAKER ROAD
EAST LONGMEADOW, MA 01028

510(k) NO: K020099
PHONE NO : 413-525-0600

DEVICE: MEGA BEAM/CERALAS NONSTERILE COLLIMATING HANDPIECE
SE DECISION MADE: 11-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMERIEUX, INC.
ATTN: RON SANYAL
100 RODOLPHE STREET
DURHAM, NC 27712

510(k) NO: K020813
PHONE NO : 919-620-2373

DEVICE: BACT/ALERT FA CULTURE BOTTLE
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMERIEUX, INC.
ATTN: RON SANYAL
100 RODOLPHE STREET
DURHAM, NC 27712

510(k) NO: K020815
PHONE NO : 919-620-2373

DEVICE: BACT/ALERT FN CULTURE BOTTLE
SE DECISION MADE: 18-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMERIEUX, INC.
ATTN: RON SANYAL
100 RODOLPHE STREET
DURHAM, NC 27712

510(k) NO: K020923
PHONE NO : 919-620-2373

DEVICE: BACT/ALERT PF CULTURE BOTTLE
SE DECISION MADE: 18-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMERIEUX, INC.
ATTN: RON SANYAL
100 RODOLPHE STREET
DURHAM, NC 27712

510(k) NO: K020931
PHONE NO : 919-620-2373

DEVICE: BACT/ALERT SA CULTURE BOTTLE
SE DECISION MADE: 18-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMERIEUX, INC.
ATTN: RON SANYAL
100 RODOLPHE STREET
DURHAM, NC 27712

510(k) NO: K021123
PHONE NO : 919-620-2373

DEVICE: BACT/ALERT SN CULTURE BOTTLE
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET ORTHOPEDICS, , INC.
ATTN: LONNIE WITHAM
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K020221
PHONE NO : 219-267-6639

DEVICE: IQL BASIC FRAGMENT PLATE SET, IQL BASIC FRAGMENT SCREW SET, IQL SMALL FRAGMENT SET, IQL MINI FRAGMENT SET
SE DECISION MADE: 02-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET ORTHOPEDICS, , INC.
ATTN: PATRICIA SANDBORN BERES
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K020905
PHONE NO : 219-267-6639

DEVICE: NBX - NON-BRIDGING EXTERNAL FIXATOR
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET ORTHOPEDICS, , INC.
FEMORAL STEM
ATTN: DALENE T BINKLEY
P.O. BOX 587
WARSAW, IN 46581-0587

510(k) NO: K020963

PHONE NO : 219-267-6639

DEVICE: TAPERLOC POROUS FEMORAL STEM & HA TAPERLOC POROUS LATERALIZED

SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: PATRICIA S BERES
56 EAST BELL DRIVE
PO BOX 587
WARSAW, IN 46581-0578

510(k) NO: K020761
PHONE NO : 574-267-6639

DEVICE: POWER TEK II
SE DECISION MADE: 03-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: MARY VERSTYNEN
P.O. BOX 587
WARSAW, IN 46581

510(k) NO: K020819
PHONE NO : 219-267-6639

DEVICE: DISTAL RADIUS PLATING SYSTEM
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOMET, INC.
ATTN: TRACY J BICKEL
56 EAST BELL DRIVE
PO BOX 587
WARSAW, IN 46581-0578

510(k) NO: K020970
PHONE NO : 574-267-6639

DEVICE: MODIFICATION TO ONCOLOGY SALVAGE SYSTEM (OSS)
SE DECISION MADE: 04-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

BIOSAFE LABORATORIES, INC.
T SYSTEM
ATTN: JACK A MAGGIORE
100 FIELD DRIVE #240
LAKE FOREST, IL 60045

510(k) NO: K012221

PHONE NO : 773-693-0400

DEVICE: SAFE AT HOME CHOLESTEROL PROFILE BLOOD COLLECTION AND TRANSPOR

SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOSOUND ESAOTE, INC.
F 3D IMAGING MODE AND MUSCULOSKELETAL INDICATION)
ATTN: COLLEEN H DENSMORE
8000 CASTLEWAY DR.
INDIANAPOLIS, IN 46250

510(k) NO: K014168

PHONE NO : 317-849-1793

DEVICE: AU6 (TECHNOS/TECHNOS MP) ULTRASOUND IMAGING SYSTEM (ADDITION C

SE DECISION MADE: 25-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOTRAC, INC.
ATTN: JAIME GUTTMAN
7215 N.W. 46TH STREET
MIAMI, FL 33166

510(k) NO: K021029
PHONE NO : 305-594-7474

DEVICE: ABP-2000 G-3
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIOTRONIK, INC.
BP; 45-JBP; 53-JBP
ATTN: JON BRUMBAUGH
6024 JEAN RD.
LAKE OSWEGO, OR 97035-5369

510(k) NO: K010281

PHONE NO : 888-345-0374

DEVICE: MEROX BIPOLAR HIGH IMPEDANCE LEAD MODELS: MEX 53/13-BP; 60/15-

SE DECISION MADE: 09-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

BIRD PRODUCTS CORP. ATTN: TOM GUTIERREZ 1100 BIRD CENTER DR. PALM SPRINGS, CA 92262	510(k) NO: K020746 PHONE NO : 760-778-7255	DEVICE: BIRD TBIRD VELA VENTILATOR SE DECISION MADE: 22-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BLACKSTONE MEDICAL, INC. ATTN: ALAN LOMBARDO 90 BROOKSDALE DR. SPRINGFIELD, MA 01104	510(k) NO: K020674 PHONE NO : 973-633-9968	DEVICE: BLACKSTONE SPINAL FIXATION SYSTEM 4.5MM MULTI-AXIAL SCREW SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BLADE WORKS, INC. ATTN: MARK MOYER 1816 TOWHEE STREET SAN MARCOS, CA 92069	510(k) NO: K020079 PHONE NO : 760-471-2427	DEVICE: BLADEWORKS MICROKERATOME BLADE, MODEL 7061 SE DECISION MADE: 19-APR-2002 510(k) STATEMENT
BOSTON SCIENTIFIC CORP. ATTN: LORRAINE M HANLEY ONE BOSTON SCIENTIFIC PL. NATICK, MA 01760-1537	510(k) NO: K020110 PHONE NO : 508-650-8172	DEVICE: MODIFICATION TO TRELEX MESH SURGICAL MESH SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. AND M00513210 ATTN: PAIGE SWEENEY ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760-1537	510(k) NO: K020765 PHONE NO : 508-652-5560	DEVICE: MICROVASIVE ZERO TIP AIRWAY RETRIEVAL BASKET, MODELS M00513200 SE DECISION MADE: 05-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ER 7, MODELS 4205 AND 4238 ATTN: KATHLEEN MORAHAN ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760-1537	510(k) NO: K020824 PHONE NO : 508-652-5942	DEVICE: SPEEDBAND SUPERVIEW SUPER 7, INJECTION SPEEDBAND SUPERVIEW SUP SE DECISION MADE: 12-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. ATTN: SUSAN POOL 2710 ORCHARD PKWY. SAN JOSE, CA 95134	510(k) NO: K021046 PHONE NO : 408-985-3608	DEVICE: COBRA CCOLED SURGICAL PROBE, MODEL 1596X SE DECISION MADE: 16-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC CORP. UR VASCULAR GRAFTS ATTN: JENNIFER BOLTON ONE BOSTON SCIENTIFIC PL. NATICK, MA 01760-1537	510(k) NO: K021213 PHONE NO : 508-652-5972	DEVICE: MODIFICATION TO HEMASHIELD PLATINUM WOVEN/MICROVEL DOUBLE VELC SE DECISION MADE: 19-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
BREG, INC. ATTN: KATHLEEN BARBER 2611 COMMERCE WAY VISTA, CA 92083	510(k) NO: K020988 PHONE NO : 760-599-3000	DEVICE: PAIN CARE 4200 SE DECISION MADE: 04-APR-2002 510(k) STATEMENT

BUSSE HOSPITAL DISPOSABLES, INC.
ATTN: JOSEPH M AZARY
P.O. BOX 2156
HUNTINGTON, CT 06484
510(k) NO: K021055
PHONE NO : 203-944-9320
DEVICE: BUSSE UMBILICAL CORD CLAMP CUTTER
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

C.R. BARD, INC.
ATTN: CAROL VIERLING
13183 HARLAND DR.
COVINGTON, GA 30014
510(k) NO: K020682
PHONE NO : 770-385-2347
DEVICE: BARD LUMINEXX 6 FR BILIARY STENT AND DELIVERY SYSTEM
SE DECISION MADE: 02-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CANE S.R.I.
ATTN: DANIEL KAMM
P.O. BOX 7007
DEERFIELD, IL 60015
510(k) NO: K013776
PHONE NO : 847-374-1727
DEVICE: MICROJET MODEL # CD4 AND CD4/20
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CANE SRL
ATTN: DANIEL KAMM
P.O. BOX 7007
DEERFIELD, IL 60015
510(k) NO: K013234
PHONE NO : 847-374-1727
DEVICE: MICROJET CRONO
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CARD GUARD SCIENTIFIC SURVIVAL, LT
ATTN: ALDEN KAY
6779 MESA RIDGE ROAD
SUITE 200
SAN DIEGO, CA 92121-2909
510(k) NO: K020825
PHONE NO : 858-777-2200
DEVICE: KING OF HEARTS EXPRESS + AF MONITOR
SE DECISION MADE: 05-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CARDIOCOMM SOLUTIONS, INC.
ATTN: ANGELA HALWAS
3060 CEDAR HILL ROAD
SUITE 201
VICTORIA, B.C.,
510(k) NO: K020366
PHONE NO : 250 744 1822
DEVICE: GLOBAL ECG MANAGEMENT SYSTEM (GEMS)
SE DECISION MADE: 30-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CARDIOVENTION, INC.
ATTN: TESSA YAMUT
3045 STENDER WAY
SANTA CLARA, CA 95054
510(k) NO: K012325
PHONE NO : 408-844-5130
DEVICE: CARDIOVENTION CORX SYSTEM, MODEL FG 0001
SE DECISION MADE: 09-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CARESIDE, INC.
ATTN: KENNETH B ASARCH
6100 BRISTOL PARKWAY
CULVER CITY, CA 90230
510(k) NO: K020488
PHONE NO : 310-338-6767
DEVICE: CARESIDE TRGLYCERIDE
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

CATHETER RESEARCH, INC.
ATTN: JOHN A STEEN
6131 WEST 80TH STREET
INDIANAPOLIS, IN 46278
510(k) NO: K020292
PHONE NO : 317-872-0074
DEVICE: UTERINE INJECTOR
SE DECISION MADE: 17-APR-2002
510(k) STATEMENT

CAVEX HOLLAND B.V. ATTN: RICHARD WOORTMAN PO BOX 852 HAARLEM (HOLLAND),	510(k) NO: K020242 PHONE NO : 312 353 07700	DEVICE: EMULATE FAST SET AND EMULATE REGULAR SET SE DECISION MADE: 17-APR-2002 510(k) STATEMENT
CHESHIRE DIAGNOSTICS LTD. ATTN: NEIL B STRINGER MANAGEMENT CENTRE, INWARD WAY ELLESMERE PORT CHESHIRE,	510(k) NO: K020694 PHONE NO : 44 151 3488023	DEVICE: QAB2A IGM ELISA KIT SE DECISION MADE: 19-APR-2002 510(k) STATEMENT
CHESHIRE DIAGNOSTICS LTD. ATTN: NEIL B STRINGER MANAGEMENT CENTRE, INWARD WAY ELLESMERE PORT CHESHIRE,	510(k) NO: K020695 PHONE NO : 44 151 3488023	DEVICE: QAB2A IGG ELISA KIT SE DECISION MADE: 19-APR-2002 510(k) STATEMENT
CHI, INC. ATTN: T. WHIT ATHEY C/O C.L. MCINTOSH 12300 TWINBROOK PKWY ROCKVILLE, MD 20852	510(k) NO: K020268 PHONE NO : 301-770-9590	DEVICE: ISAAC 1.5 T MR SYSTEM SE DECISION MADE: 25-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CIBA VISION CORP. ATTN: STEVEN DOWDLEY 11460 JOHNS CREEK PKWY. DULUTH, GA 30097	510(k) NO: K013204 PHONE NO : 678-415-3897	DEVICE: AQUIFY LENS COMFORT DROPS SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CIBA VISION CORP. DESIGN ATTN: ALICIA M PLESNARSKI 11460 JOHNS CREEK PKWY. DULUTH, GA 30097	510(k) NO: K020139 PHONE NO : 678-415-3924	DEVICE: FOCUS EXCELENS (LOTRAFILCON B) SPHERICAL, TORIC AND MULTIFOCAL SE DECISION MADE: 09-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CIMEX BIOTECH, LLC. ATTN: MICHAEL HAAS 72385 INDUSTRY PARK COVINGTON, LA 70435	510(k) NO: K012214 PHONE NO : 504-871-0802	DEVICE: CRYOPEN AND ACCESSORIES SE DECISION MADE: 26-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CIRCON VIDEO CYSTOURETEROSCOPE, MODELS MR-9, MR-9L, ATTN: WAYNE STERNER 6500 HOLLISTER AVE. SANTA BARBARA, CA 93117	510(k) NO: K012758 PHONE NO : 805-685-5100	DEVICE: URETEROSCOPE, PEDIATRIC CYSTOURETEROSCOPE, OPERATING PEDIATRIC SE DECISION MADE: 09-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CLEAR MEDICAL, INC. ATTN: RICHARD RADFORD 1776 136TH PL. NE BELLEVUE, WA 98005	510(k) NO: K012604 PHONE NO : 425-401-1414	DEVICE: CLEARMEDICAL/RADI FEMOSTOP COMPRESSION SYSTEM, MODEL 017500 SE DECISION MADE: 19-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

COMPEX S.A. ATTN: ANSIS M HELMANIS 1225 EYE STREET, N.W. WASHINGTON, DC 20005	510(k) NO: K011880 PHONE NO : 202-457-0300	DEVICE: COMPEX SPORT SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CONMED CORP. NMED ESU CART, REF: 60-6120 ATTN: CHARLES M HART 14603 FREMONT AVE. CENTENNIAL, CO 80112	510(k) NO: K020135 PHONE NO : 303-699-7600	DEVICE: CONMED SYSTEM 2000 ELECTROSURGICAL GENERATOR, REF: 60-8002; CC SE DECISION MADE: 12-APR-2002 510(k) STATEMENT
CONMED CORP. ATTN: CHARLES M (MIKE) HART 14603 FREMONT AVE. CENTENNIAL, CO 80112	510(k) NO: K020186 PHONE NO : 303-699-7600	DEVICE: CONMED SYSTEM 5000 ESU SE DECISION MADE: 12-APR-2002 510(k) STATEMENT
COOK BIOTECH, INC. ATTN: MARK BLEYER 3055 KENT AVE. WEST LAFAYETTE, IN 47906-1076	510(k) NO: K020654 PHONE NO : 765-497-3355	DEVICE: STRATASIS SLING KIT SE DECISION MADE: 09-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COOK OB/GYN ATTN: CINDY RUMPLE 1100 W. MORGAN STREET SPENCER, IN 47460	510(k) NO: K013597 PHONE NO : 812-829-6500	DEVICE: TAMPONADE UTERINE BALLOON CATHETER SET SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COOK VASCULAR, INC. ATTN: THOMAS J KARDOS P.O. BOX 529 LEECHBURG, PA 15656	510(k) NO: K010128 PHONE NO : 724-845-8621	DEVICE: COOK VASCULAR PEEL-AWAY HEMOSTASIS VALVE SE DECISION MADE: 25-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COOK, INC. ATTN: LISA HOPKINS 925 SOUTH CURRY PIKE P.O. BOX 489 BLOOMINGTON, IN 47402	510(k) NO: K013865 PHONE NO : 800-346-2686	DEVICE: TIP DEFLECTING ENDOBRONCHIAL BLOCKER SE DECISION MADE: 22-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
COOPERVISION, INC. FOR DAILY WEAR ATTN: BONNIE TSYMBAL 711 NORTH RD. SCOTTSVILLE, NY 14546	510(k) NO: K020392 PHONE NO : 585-264-3210	DEVICE: FREQUENCY 55 UV (METHAFILCON A) SOFT (HYDROPHLIC) CONTACT LENS SE DECISION MADE: 26-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
CORDIS CORP. NT ATTN: DONNA MARSHALL 7 POWDER HORN DRIVE WARREN, NJ 07059	510(k) NO: K020809 PHONE NO : 908-412-3844	DEVICE: MODIFICATION TO CORDIS PALMAZ GENESIS TRANSHEPATIC BILIARY STE SE DECISION MADE: 12-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

CYLEX, INC.
ATTN: JUDI SMITH
P.O. BOX 103
BALDWIN, MD 21013

510(k) NO: K013169
PHONE NO : 410-592-2060

DEVICE: IMMUNE CELL FUNCTION ASSAY
SE DECISION MADE: 02-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, , INC.
ICILLIN/SULBACTAM
ATTN: MAUREEN MENDE
2040 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020319
PHONE NO : 916-374-3174

DEVICE: MICROSCAN RAPID/S PLUS GRAM-NEGATIVE MIC/COMBO PANELS WITH AMP

SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE BEHRING, , INC.
ERACILLIN
ATTN: MAUREEN MENDE
2040 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020397
PHONE NO : 916-374-3174

DEVICE: MICROSCAN RAPID/S PLUS GRAM-NEGATIVE MIC/COMBO PANELS WITH PIP

SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE MICROSCAN, INC.
TRIAXONE (0.5 , 2 - 128 UG/ML
ATTN: MAUREEN MENDE
1584 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020506
PHONE NO : 916-374-3174

DEVICE: MICROSCAN RAPID/S PLUS GRAM-NEGATIVE MIC/COMBO PANELS WITH CEF

SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE MICROSCAN, INC.
ATTN: CYNTHIA VAN DUKER
1584 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020556
PHONE NO : 916-374-3105

DEVICE: MICROSCAN MICROSTREP PLUS PANEL WITH LEVOFLOXACIN
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE MICROSCAN, INC.
ATTN: CYNTHIA VAN DUKER
1584 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020626
PHONE NO : 916-374-3105

DEVICE: MICROSCAN MICROSTREP PLUS PANEL NEW ANTIMICROBIAL-PENICILLIN
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE MICROSCAN, INC.
IM/SULFAMETHOXAZOLE
ATTN: CYNTHIA VAN DUKER
1584 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020686
PHONE NO : 916-374-3105

DEVICE: MICROSCAN MICROSTREP PLUS PANEL NEW ANTIMICROBIAL - TRIMETHOPR

SE DECISION MADE: 30-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DADE MICROSCAN, INC.
ATTN: CYNTHIA VAN DUKER
1584 ENTERPRISE BLVD.
WEST SACRAMENTO, CA 95691

510(k) NO: K020691
PHONE NO : 916-374-3105

DEVICE: MICROSCAN MICROSTREP PLUS PANEL NEW ANTIMICROBIAL - CEFACLOR
SE DECISION MADE: 30-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DAN MED, INC.
ATTN: THOMAS SANDGAARD
4 WEST DRY CREEK CIRCLE,
SUITE 260
DENVER, CO 80120

510(k) NO: K013210
PHONE NO : 800-495-6670

DEVICE: TRUWAVE
SE DECISION MADE: 04-APR-2002

510(k) STATEMENT

DATASCOPE CORP.
; DATASCOPE'S TRUE SHEATHLESS DL 9.5 FR. IAB; DATASCOPE'S
ATTN: JOANN WOLF
15 LAW DR.
FAIRFIELD, NJ 07004-3206

510(k) NO: K020257
PHONE NO : 973-244-6123

DEVICE: DATASCOPE'S 8FR. ALT B IAB; DATASCOPE'S PROFILE 8FR. ALT B IAB

SE DECISION MADE: 24-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DENT CORP. RESEARCH & DEVELOPMENT
ATTN: DAVID ABELDA
7-11 S. BROADWAY
WHITE PLAINS, NY 10601

510(k) NO: K020206
PHONE NO : 914-682-6600

DEVICE: INTRAORAL CAMERA ME-15
SE DECISION MADE: 11-APR-2002
510(k) STATEMENT

DEPILASE GROUP LTD.
ATTN: MARIO RUSSO
ONE CANADA SQUARE
CANARY WHARF
LONDON,

510(k) NO: K020697
PHONE NO : 442 077 121675

DEVICE: DEPILASE TWIN YAG LASER SYSTEM
SE DECISION MADE: 12-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

DIASOL, INC.
ATTN: MONICA ABELES
13212 RAYMER ST.
NORTH HOLLYWOOD, CA 91605

510(k) NO: K020230
PHONE NO : 818-255-1800

DEVICE: DIASOL-BICARB
SE DECISION MADE: 23-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

DIDECO S.P.A.
ATTN: BARRY SALL
195 WEST STREET
WALTHAM, MA 02451-1163

510(k) NO: K020997
PHONE NO : 781-434-4742

DEVICE: APEX PH.I.S.I.O. ADULT HOLLOW FIBER MEMBRANE OXYGENATOR
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020468
PHONE NO : 608-877-2635

DEVICE: CHIN ELECTRODE
SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

E.S.W.L. PRODUCTS, INC.
ATTN: DANIEL KAMM
PO BOX 7007
DEERFIELD, IL 60015

510(k) NO: K013471
PHONE NO : 847-374-1727

DEVICE: "DELTA 2000" SERIES EXTRACORPOREAL LITHOTRIPTER
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

EASTERN CRANIAL AFFILIATES
ATTN: JOSEPH TERPENNING
2525 NORTH TENTH STREET # 804
ARLINGTON, VA 22201

510(k) NO: K020448
PHONE NO : 703-516-4340

DEVICE: STATIC CRANIOPLASTY ORTHOSIS
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

EBI, L.P.
ATTN: PATRICIA FLOOD
100 INTERPACE PKWY.
PARSIPPANY, NJ 07054-1079

510(k) NO: K020681
PHONE NO : 973-299-9300

DEVICE: EBI OMEGA21 SPINAL FIXATION SYSTEM
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ECHOTECH 3D IMAGING SYSTEMS, INC. 510(k) NO: K013088 DEVICE: ECHOTECH EASY 3D FAMILY, ECHOTECH 3D FREESCAN, ECHOTECH EASYARCHIVE, ECHOTECH QUANTICON, ECHOTECH EASYSTRESS
ATTN: KEVIN MORNINGSTAR PHONE NO : 303-697-8198 SE DECISION MADE: 04-APR-2002
PO BOX 218 510(k) SUMMARY AVAILABLE FROM FDA
INDIAN HILLS, CO 80454

ECI MEDICAL TECHNOLOGIES, INC. 510(k) NO: K020918 DEVICE: ELASTYFREE SYNTHETIC POWDER-FREE SURGICAL GLOVE
ATTN: SHIRANTHA SAMARAPPULI PHONE NO : 902 543 6665 SE DECISION MADE: 19-APR-2002
2 COOK RD. 510(k) STATEMENT
BRIDGEWATER, NOVA SCOTIA,

EDWARDS LIFESCIENCES, LLC. 510(k) NO: K002578 DEVICE: AXILLARY ACCESS ARTERIAL CANNULA
ATTN: KAREN JONES PHONE NO : 801-565-6231 SE DECISION MADE: 11-APR-2002
6864 SOUTH 300 WEST 510(k) SUMMARY AVAILABLE FROM FDA
MIDVALE, UT 84047

EDWARDS LIFESCIENCES, LLC. 510(k) NO: K020864 DEVICE: EDWARDS MC TRICUSPID ANNULOPLASTY SYSTEM, MODEL 4900
ATTN: SUSAN REYNOLDS PHONE NO : 949-250-2482 SE DECISION MADE: 17-APR-2002
ONE EDWARDS WAY 510(k) SUMMARY AVAILABLE FROM FDA
IRVINE, CA 92614-5686

EFILM MEDICAL, INC. 510(k) NO: K020995 DEVICE: EFILM WORKSTATION WITH MODULES
ATTN: JOSEPH A THOMAS PHONE NO : 416 204 9664 X291 SE DECISION MADE: 12-APR-2002
500 UNIVERSITY AVE., SUITE 300 510(k) SUMMARY AVAILABLE FROM FDA
TORONTO, ONTARIO,

ELAN DIAGNOSTICS 510(k) NO: K020575 DEVICE: ATAC DIRECT LDL REAGENT AND ATAC DIRECT LDL CALIBRATOR KITS
ATTN: WYNN STOCKING PHONE NO : 714-672-3553 SE DECISION MADE: 12-APR-2002
1075 W. LAMBERT RD., SUITE D 510(k) SUMMARY AVAILABLE FROM FDA
BREA, CA 92821

ENGINEERED MEDICAL SYSTEMS 510(k) NO: K013122 DEVICE: EMS ELECTROSTATIC FLITER AND HME COMBINATION
ATTN: PAUL DRYDEN PHONE NO : 317-335-3780 SE DECISION MADE: 19-APR-2002
6329 W. WATERVIEW CT. 510(k) SUMMARY AVAILABLE FROM FDA
MCCORDSVILLE, IN 46055-9501

EP TECHNOLOGIES, INC. 510(k) NO: K013349 DEVICE: ASTRONOMER PLUS SYSTEM
ATTN: ANDREA L RUTH PHONE NO : 408-895-3500 SE DECISION MADE: 09-APR-2002
2710 ORCHARD PKWY. 510(k) SUMMARY AVAILABLE FROM FDA
SAN JOSE, CA 95113

ETHICON ENDO-SURGERY, INC. 510(k) NO: K020276 DEVICE: 8 GAUGE MICROMARK II TISSUE MARKER, MODELS C1540 & C1535
ATTN: GEORGE C ABERNATHY PHONE NO : 513-337-3179 SE DECISION MADE: 12-APR-2002
4545 CREEK RD. 510(k) SUMMARY AVAILABLE FROM FDA
CINCINNATI, OH 45242-2839

EVANS MEDICAL, INC. ATTN: DANIEL KAMM P.O. BOX 7007 DEERFIELD, IL 60015	510(k) NO: K020530 PHONE NO : 847-374-1727	DEVICE: EVANS SUB-Q, MODEL MC4206 SE DECISION MADE: 29-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
FRIADENT GMBH ATTN: CAROL PATTERSON 21911 ERIE LANE LAKE FOREST, CA 92630	510(k) NO: K013067 PHONE NO : 949-462-0900	DEVICE: FRIALOC DENTAL IMPLANT SYSTEM SE DECISION MADE: 09-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GARAVENTA ACCESSIBILITY ATTN: NORM COOPER BOX 1769 BLAIN, WA 98231-1769	510(k) NO: K020933 PHONE NO : 800-663-6556	DEVICE: GARAVENTA SUPER-TRAC TRE-52 SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GC AMERICA, INC. ATTN: TERRY L JORITZ 3737 WEST 127TH ST. ALSIP, IL 60803	510(k) NO: K020578 PHONE NO : 708-926-3105	DEVICE: GC FUJI ORTHO BAND PASTE PAK SE DECISION MADE: 26-APR-2002 510(k) STATEMENT
GE MEDICAL SYSTEMS ATTN: 283 RUE DE LA MINIERE BP 34 BUC CEDEX,	510(k) NO: K020929 PHONE NO :	DEVICE: SMARTSCORE 3.5; SMARTSCORE 4.0; SMARTSCORE 4.5 SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GE OEC MEDICAL SYSTEMS ATTN: BILL GISLASON 384 WRIGHT BROTHERS DR. SALT LAKE CITY, UT 84116	510(k) NO: K021049 PHONE NO : 801-536-4520	DEVICE: OEC 9800 PLUS DIGITAL MOBILE IMAGING SYSTEM SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GENERAL ELECTRIC CO. ATTN: ALLEN SCHUH P.O. BOX 414 MILWAUKEE, WI 53201	510(k) NO: K020789 PHONE NO : 414-647-4385	DEVICE: GE VIVID 3 EXPERT; GE VIVID 3 PRO SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GISH BIOMEDICAL, INC. NGER ATTN: JAMES H KNAUSS 11874 SOUTH EVELYN CIRCLE HOUSTON, TX 77071	510(k) NO: K020106 PHONE NO : 713-723-4080	DEVICE: VISION BLOOD CARDIOPLEGIA SYSTEM AND EXTRACORPOREAL HEAT EXCHA SE DECISION MADE: 10-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GLOBAL TREASURE LTD. ATTN: BEN MA BLOCK2, 5/F,. ROOM 8 NAN FUNG IND. CITY 18 TIN HAU ROAD, TUEN MUN N.T.,	510(k) NO: K021028 PHONE NO : 852 145 41883	DEVICE: MODEL GT980201 ELECTRONIC THERMOMETER SE DECISION MADE: 08-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

GLOBAL TREASURE LTD. ATTN: BLOCK2, 5/F,. ROOM 8 NAN FUNG IND. CITY 18 TIN HAU ROAD, TUEN MUN N.T.,	510(k) NO: K021052 PHONE NO :	DEVICE: MODEL GI010706 ELECTRONIC THERMOMETER SE DECISION MADE: 09-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
GREAT GLOVE SDN BHD ABELLING CLAIMS (50 MICROGRAMS OR LESS) ATTN: NOOR AKILAH 24, JALAN RAJA MOKHTAR DUA KAPAR, SELANGOR D.E.,	510(k) NO: K020363 PHONE NO : 603 325 00646	DEVICE: GREAT GLOVE LATEX EXAMINATION POWDERFREE GLOVES WITH PROTEIN L SE DECISION MADE: 10-APR-2002 510(k) STATEMENT
GYRUS ENT L.L.C. ATTN: JEFFREY W COBB 2925 APPLING RD BARTLETT, TN 38133	510(k) NO: K020067 PHONE NO : 901-373-2673	DEVICE: GYRUS ENT SOMNOPLASTY GENERATOR SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
H & A CONSULTANTS ATTN: SCOTT HENDERSON 2584 SADDLEWOOD LANE PALM HARBOR, FL 34685	510(k) NO: K020146 PHONE NO : 727-773-0414	DEVICE: SERRALNYL SE DECISION MADE: 15-APR-2002 510(k) STATEMENT
H & A CONSULTANTS ATTN: SCOTT HENDERSON 2584 SADDLEWOOD LANE PALM HARBOR, FL 34685	510(k) NO: K020901 PHONE NO : 727-773-0414	DEVICE: SERRALSILK SE DECISION MADE: 26-APR-2002 510(k) STATEMENT
HAKKO MEDICAL CO., LTD. ATTN: MSHIRO KITAGAWA 7-9 KAMIMEGURO 1-CHOME MEGURO-KU, TOKYO,	510(k) NO: K013108 PHONE NO : 81 3 4648500	DEVICE: BIOSUC SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HAKKO SHOJI CO., LTD. #LD112 ATTN: ELIZABETH MILLER 4545 CREEK ROAD CINCINNATI, OH 45242-2839	510(k) NO: K020307 PHONE NO : 513-337-7146	DEVICE: LAP DISC 120 X 120MM X 2CM #LD111; LAP DISC 120 X 120MM X 7CM SE DECISION MADE: 26-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HARVEST TECHNOLOGIES, CORP. ATTN: JOHN D BONASERA 40 GRISSOM RD, SUITE 100 PLYMOUTH, MA 02360	510(k) NO: K020252 PHONE NO : 508-732-7530	DEVICE: SMARTJET GRAFTING LIQUID APPLICATOR, MODELS SK/S & LK/2 SE DECISION MADE: 05-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HAYES MEDICAL, INC. ATTN: WILLIAM J GRIFFIN 1115 WINDFIELD WAY, SUITE 100 EL DORADO HILLS, CA 95762-9623	510(k) NO: K020153 PHONE NO : 916-355-7156	DEVICE: CONSENSUS ACETABLAR SHELL, TI COATED SE DECISION MADE: 15-APR-2002 510(k) STATEMENT

HEALTH & LIFE CO., LTD. ATTN: SUSAN CHEN 6F,NO. 407, CHUNG SHAN RD. SEC.02, CHUNG HO CITY TAIPEI HSIEN,	510(k) NO: K020766 PHONE NO : 886 232 349600	DEVICE: HL168F SE DECISION MADE: 05-APR-2002 510(k) STATEMENT
HEARING INNOVATIONS, INC. ATTN: GERARD J PRUD'HOMME COLUMBIA SQUARE 555 THIRTEENTH STREET, NW WASHINGTON, DC 20004-1109	510(k) NO: K013253 PHONE NO : 202-637-5910	DEVICE: HISONIC-TRD TINNITUS RELIEF DEVICE SE DECISION MADE: 05-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HEMOCUE, INC. ATTN: R.J. SLOMOFF 9229 CRANFORD DRIVE POTOMAC, MD 20854	510(k) NO: K020935 PHONE NO : 301-983-1707	DEVICE: HEMOCUE GLUCOSE 201 SYSTEM, ARTICLE NUMBER 120706 SE DECISION MADE: 03-APR-2002 510(k) STATEMENT
HOMMED LLC. ATTN: TOMMIE J MORGAN 2018 NORTH DURHAM DRIVE HOUSTON, TX 77008	510(k) NO: K014025 PHONE NO : 713-880-5111	DEVICE: HOMMED SENTRY III PATIENT MONITOR SYSTEM WITH CARD READER SE DECISION MADE: 09-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOMMED LLC. ATTN: TOMMIE J MORGAN 2018 NORTH DURHAM DRIVE HOUSTON, TX 77008	510(k) NO: K020184 PHONE NO : 713-880-5111	DEVICE: HOMMED CENTRAL STATION SE DECISION MADE: 22-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOSUK CO., LTD. ATTN: CAROLE STAMP 5353 WAYZATA BLVD., STE 505 MINNEAPOLIS, MN 55416	510(k) NO: K021197 PHONE NO : 952-946-8080	DEVICE: SUREONE INSULIN SYRINGE, 31 GAUGE X 5/16" SE DECISION MADE: 26-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOVEROUND CORP. ATTN: TONY DIGIOVANNI 2151 WHITFIELD INDUSTRIAL WAY SARASOTA, FL 34243	510(k) NO: K021136 PHONE NO : 941-739-6200	DEVICE: TEKNIQUE-HOVEROUND POWER WHEEL CHAIR SE DECISION MADE: 19-APR-2002 510(k) STATEMENT
HOWMEDICA OSTEONICS CORP. ATTN: WILLIAMR J CYMBALUK 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K013106 PHONE NO : 201-825-4900	DEVICE: 2 PIECE MODULAR HIP STEM SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: KAREN ARIEMMA 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020773 PHONE NO : 201-760-8187	DEVICE: LONG LENGTH GAMMA NAIL SE DECISION MADE: 04-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

HOWMEDICA OSTEONICS CORP. ATTN: MARGARET F CROWE 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020841 PHONE NO : 201-831-5580	DEVICE: AVON PATELLAR COMPONENT SE DECISION MADE: 11-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: JENNIFER A DAUDELIN 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K020989 PHONE NO : 201-831-5379	DEVICE: SUPER EON PLUS FEMORAL STEMS SE DECISION MADE: 26-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: KAREN ARIEMMA 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K021026 PHONE NO : 201-760-8187	DEVICE: S2 FEMORAL NAIL SE DECISION MADE: 25-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: KAREN ARIEMMA 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K021027 PHONE NO : 201-760-8187	DEVICE: S2 TIBIAL NAIL SE DECISION MADE: 25-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HUNTLEIGH DIAGNOSTICS LTD. ATTN: AUDREY WITKO 40 CHRISTOPHER WAY EATONTOWN, NJ 07724-3327	510(k) NO: K020390 PHONE NO : 800-223-1218	DEVICE: MODIFICATION TO FETAL ASSIST SE DECISION MADE: 19-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HYDROCISION, INC. ATTN: DEBBIE IAMPIETRO 7 TIFFANY TRAIL HOPKINTON, MA 01748	510(k) NO: K020688 PHONE NO : 508-259-7374	DEVICE: HYDROCISION ARTHOJET SYSTEM WITH CAUTERY AND TURBOBURR SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HYGIA HEALTH SERVICES, INC. 5329, 5330, 5345, 5480 ATTN: GEOFF M FATZINGER 2800 MILAN CT., SUITE 259 BIRMINGHAM, AL 35211	510(k) NO: K012417 PHONE NO : 205-943-6670	DEVICE: HYGIA HEALTH SERVICE REPROCESSED KENDALL SCD SLEEVE, MODELS # SE DECISION MADE: 08-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HYGIA HEALTH SERVICES, INC. ATTN: GEOFF M FATZINGER 2800 MILAN CT., SUITE 259 BIRMINGHAM, AL 35211	510(k) NO: K012650 PHONE NO : 205-943-6670	DEVICE: HYGIA HEALTH SERVICES REPROCESSED NUTECH FOOT WRAP SE DECISION MADE: 12-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
HYGIA HEALTH SERVICES, INC. G 100, FG 200 ATTN: GEOFF M FATZINGER 2800 MILAN CT., SUITE 259 BIRMINGHAM, AL 35211	510(k) NO: K012651 PHONE NO : 205-943-6670	DEVICE: HYGIA HEALTH SERVICES REPROCESSED HUNTLEIGH FOOT WRAP MODELS F SE DECISION MADE: 12-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

HYGIA HEALTH SERVICES, INC. 510(k) NO: K012654
E MODELS DVT10, DVT 20, DVT 30, DVT 40
ATTN: GEOFF M FATZINGER PHONE NO : 205-943-6670
2800 MILAN CT., SUITE 259
BIRMINGHAM, AL 35211

DEVICE: HYGIA HEALTH SERVICES REPROCESSED HUNTLEIGH FLOWIRON DVT SLEEV
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

HYGIA HEALTH SERVICES, INC. 510(k) NO: K012657
ATTN: GEOFF M FATZINGER PHONE NO : 205-943-6670
2800 MILAN CT., SUITE 259
BIRMINGHAM, AL 35211

DEVICE: HYGIA HEALTH SERVICES REPROCESSED NUTECH CALF WRAP
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

HYGIA HEALTH SERVICES, INC. 510(k) NO: K012956
MB AND RIGHT LIMB
ATTN: GEOFF M FATZINGER PHONE NO : 205-943-6670
2800 MILAN CT., SUITE 259
BIRMINGHAM, AL 35211

DEVICE: HYGIA HEALTH SERVICES REPROCESSED NU TECH COMBO, MODEL LEFT LI
SE DECISION MADE: 11-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

IMMUNETECH CORPORATION 510(k) NO: K020387
ATTN: VIVIANNE NOETZEL PHONE NO : 858-756-8483
P.O. BOX 9433
17394 VIA DEL BRAVO
RANCHO SANTA FE, CA 92067

DEVICE: MYALLERGYTEST SYSTEM
SE DECISION MADE: 17-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

IMTEC CORP. 510(k) NO: K020396
ATTN: M.K. PATTERSON PHONE NO : 405-223-4456
2401 NORTH COMMERCE
ARDMORE, OK 73401

DEVICE: BIOCELLECT -PERIO
SE DECISION MADE: 10-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

INOVA DIAGNOSTICS, INC. 510(k) NO: K020414
ATTN: BRYS C MYERS PHONE NO : 858-586-9900
10180 SCRIPPS RANCH BLVD.
SAN DIEGO, CA 92131

DEVICE: QUANTA LITE CCP ELISA
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

INTRALUMINAL THERAPEUTICS, INC. 510(k) NO: K011986
ATTN: PAMELA L MISAJON PHONE NO : 760-918-1820
6354 CORTE DEL ABETO
SUITE A
CARLSBAD, CA 92009

DEVICE: SAFE-STEER GUIDE WIRE SYSTEM
SE DECISION MADE: 03-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

IVOCLAR VIVADENT, INC. 510(k) NO: K020253
ATTN: ANDERJEET GULATI PHONE NO : 716-691-0010
175 PINEVIEW DR.
AMHERST, NY 14228

DEVICE: 4 ALL (DW286A)
SE DECISION MADE: 17-APR-2002
510(k) STATEMENT

JAS DIAGNOSTIC, INC. 510(k) NO: K020454
ATTN: DAVID JOHNSTON PHONE NO : 305-418-2320
7220 NW 58TH ST.
MIAMI, FL 33166

DEVICE: CHEMISTRY CALIBRATOR
SE DECISION MADE: 08-APR-2002
510(k) STATEMENT

JENERIC/PENTRON, INC.
ATTN: ANNMARIE TENERO
53 NORTH PLAINS INDUSTRIAL RD.
WALLINGFORD, CT 06492-0724

510(k) NO: K020499
PHONE NO : 203-265-7397

DEVICE: BOND-3 ADHESIVE
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

JOMED AG
ATTN: CHRISTINA KICHULA
1700 ROCKVILLE PIKE, SUITE 400
ROCKVILLE, MD 20852

510(k) NO: K020854
PHONE NO : 301-998-6151

DEVICE: MODIFICATION TO FOX PTA CATHETER
SE DECISION MADE: 11-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020515
PHONE NO : 610-932-7738

DEVICE: JOSTRA ANTEGRADE CARDIOPLEGIA CANNULA
SE DECISION MADE: 24-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K011793
PHONE NO : 310-410-2769

DEVICE: KSEA FIBERSCOPE
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020303
PHONE NO : 714-516-7484

DEVICE: XR PRIMER 2
SE DECISION MADE: 19-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

L.A.M. PHARMACEUTICAL, CORP.
ATTN: CLAWSON BOWMAN
1330A REDWOOD WAY
PETALUMA, CA 94954

510(k) NO: K020325
PHONE NO : 707-793-2600

DEVICE: L.A.M. IPM WOUND GEL
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

LIN-ZHI INTERNATIONAL, INC.
ATTN: CHIU CHIN CHANG
2391 ZANKER RD., SUITE 340
SAN JOSE, CA 95131-1124

510(k) NO: K020769
PHONE NO : 408-944-0360

DEVICE: SINGLE ANALYTE URINE DRUGS OF ABUSE CALIBRATORS AND CONTROLS
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K013369
PHONE NO : 727-399-5234

DEVICE: RESECTION ABLATOR
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MACHNET BV
ATTN: DANIEL KAMM
PO BOX 7007
DEERFIELD, IL 60015

510(k) NO: K020289
PHONE NO : 847-374-1727

DEVICE: MICS INTERVENTION AID, CATALOG # MICS-MIA AND MICS-MIAS
SE DECISION MADE: 24-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MEDICAL ANALYSIS SYSTEMS, INC.
ATTN: PENNY M LAYMAN
5300 ADOLFO RD.
CAMARILLO, CA 93012

510(k) NO: K021155

PHONE NO : 805-987-7891

DEVICE: MAS UA CONTROL, DADE UA CONTROL- LIQUID ASSAYED URINALYSIS CONTROL

SE DECISION MADE: 29-APR-2002
510(k) STATEMENT

MEDICAL INSTRUMENT DEVELOPMENT LAB
ATTN: LINDA M UPTON
14477 CATALINA ST.
SAN LEANDRO, CA 94577

510(k) NO: K020911
PHONE NO : 510-357-3952

DEVICE: MID LABS AUTONOMOUS VIT ENHANCER (AVE)
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC PERFUSION SYSTEMS
LA TIP
ATTN: LUCY TAN
7611 NORTHLAND DR. N
MINNEAPOLIS, MN 55428

510(k) NO: K020147
PHONE NO : 763-391-9000

DEVICE: MAGELLAN RATIO DISPENSER KIT/MAGELLAN SPRAY TIP/MAGELLAN CANNU

SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MEDTRONIC, INC.
ATTN: KRISTY K MOLLNER
7000 CENTRAL AVE. N.E.
MINNEAPOLIS, MN 55432-3576

510(k) NO: K013517
PHONE NO : 763-514-4189

DEVICE: 10600 DEFLECTABLE CATHETER SYSTEM, MODEL 10600
SE DECISION MADE: 25-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MEGADYNE MEDICAL PRODUCTS, INC.
ATTN: RONDA K MAGNESON
11506 SOUTH STATE ST.
DRAPER, UT 84020

510(k) NO: K021077
PHONE NO : 801-576-9669

DEVICE: MEGA 2000 SOFT PATIENT RETURN ELECTRODE PAD
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MICK RADIO-NUCLEAR INSTRUMENTS, IN
ATTN: FELIX MICK
521 HOMESTEAD AVE.
MOUNT VERNON, NY 10550

510(k) NO: K020176
PHONE NO : 914-667-3999

DEVICE: HDR MIAMI APPLICATOR
SE DECISION MADE: 08-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MICRO THERAPEUTICS, INC.
ATTN: TOM DAUGHTERS
2 GOODYEAR
IRVINE, CA 92618

510(k) NO: K021139
PHONE NO : 949-837-3700

DEVICE: TRULINE REINFORCED VALVED INFUSION CATHETER
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MILLIPORE CORP.
ATTN: THOMAS BORROWS
80 ASHBY RD.
BEDFORD, MA 01730

510(k) NO: K013988
PHONE NO : 781-533-2622

DEVICE: MILLEX GP STERILIZING FILTER UNIT, MODEL SLGP 033 R
SE DECISION MADE: 04-APR-2002
510(k) STATEMENT

MIRADA SOLUTIONS LTD
ATTN: ROGER W BARNES
342 SUNSET BAY ROAD
HOT SPRINGS, AR 71913

510(k) NO: K020546
PHONE NO : 501-525-8612

DEVICE: FUSION 7D
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MISSION DIAGNOSTICS
ATTN: LINDA STUNDINER
331 FISKE ST.
HOLLISTON, MA 01746

510(k) NO: K020894
PHONE NO : 508-429-0450

DEVICE: CALIBRATING MATERIAL, CAL-PAK, BUFFERS
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

MONOBIND ATTN: JAY SINGH 729 WEST 16TH ST., C-4 COSTA MESA, CA 92627	510(k) NO: K020548 PHONE NO : 949-642-4830	DEVICE: FREE T4 (THYTOXINE) MICROPLATE EIA TEST MODELS # 1225-300 SE DECISION MADE: 05-APR-2002 510(k) STATEMENT
NAKANISHI, INC. ATTN: HIROJI SEKIGUCHI 700 SHIMOHINATA KANUMA-SHI, TOCHIGI-KEN,	510(k) NO: K020327 PHONE NO : 011 812 89643422	DEVICE: SURGIC IV IMPLANT CONTROL UNIT SE DECISION MADE: 08-APR-2002 510(k) STATEMENT
NELLCOR PURITAN BENNETT, INC. ATTN: GINA TO 4280 HACIENDA DR. PLEASANTON, CA 94588-2719	510(k) NO: K020604 PHONE NO : 925-463-4427	DEVICE: WARMTOUCH PATIENT WARMING SYSTEM, MODEL 5300 SE DECISION MADE: 23-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NEUSOFT DIGITAL MEDICAL SYSTEM CO. ATTN: WANG ZHIQIANG NO.3-11, WENHUA ROAD HEPING DISTRICT SHENYANG, LIAONING,	510(k) NO: K020913 PHONE NO : 86 24 23783000	DEVICE: CT-C3000 SPIRAL CT SCANNER SYSTEM SE DECISION MADE: 03-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NICOLET BIOMEDICAL, INC. ATTN: GARY SYRING 800 LEVANGER LANE STOUGHTON, WI 53589	510(k) NO: K020218 PHONE NO : 608-877-2635	DEVICE: SNAP EEG MONITOR SE DECISION MADE: 22-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NICOLET BIOMEDICAL, INC. ATTN: GARY SYRING 800 LEVANGER LANE STOUGHTON, WI 53589	510(k) NO: K020955 PHONE NO : 608-877-2635	DEVICE: NICOLET ELECTROCAUTERY DETECTOR SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NICOLET VASCULAR, INC. ATTN: DAVID W WAGNER 6355 JOYCE DR. GOLDEN, CO 80403	510(k) NO: K013281 PHONE NO : 303-431-9400	DEVICE: VERSALAB APM SE DECISION MADE: 18-APR-2002 510(k) STATEMENT
NIDEK, INC. ATTN: CAROL PATTERSON 21911 ERIE LANE LAKE FOREST, CA	510(k) NO: K014274 PHONE NO : 949-462-0900	DEVICE: NON-MYDRIATIC FUNDUS CAMERA, MODEL NM-1000 SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA
NXSTAGE MEDICAL, INC. ATTN: NORMA LEMAY 439 SOUTH UNION STREET SUITE 501 LAWRENCE, MA 01843	510(k) NO: K020858 PHONE NO : 978-687-4700	DEVICE: NXSTAGE THERAPY SYSTEM SE DECISION MADE: 17-APR-2002 510(k) SUMMARY AVAILABLE FROM FDA

OCU-EASE OPTICAL PRODUCTS, INC.
ATTN: CHARLES R VERMETTE
629 TENNENT AVE.
PINOLE, CA 94564

510(k) NO: K020690
PHONE NO : 510-724-0384

DEVICE: OCU-FLEX-53 CUSTOM PROSTHETIC (OCUFILCON B) SOFT CONTACT LENS
SE DECISION MADE: 26-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ODIN MEDICAL TECHNOLOGIES LTD.
ATTN: ADI ICKOWICZ
P.O. BOX 248
YOKNEAM ELIT,

510(k) NO: K020601
PHONE NO : 972 495 91010

DEVICE: FLEXICOIL - MALLEABLE RECEIVE-ONLY SURFACE COIL
SE DECISION MADE: 24-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

OHIO MEDICAL INSTRUMENT CO., INC.
SS SYSTEM
ATTN: DONALD A LINCOLN
10 OAK POINT
WRENTHAM, MA 02093

510(k) NO: K013428
PHONE NO : 508-384-2506

DEVICE: MAYFIELD/ACCISS OPERATING ARM SYSTEM AND MAYFIELD/OPTICAL ACCI

SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ORASURE TECHNOLOGIES, INC.
ATTN: R. SAM NIEDBALA
1745 EATON AVE
BETHLEHEM, PA 18018-1799

510(k) NO: K013882
PHONE NO : 610-882-1820

DEVICE: OTI BENZODIAZEPINES INTERCEPT MICRO-PLATE EIA MODEL #1110I
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ORASURE TECHNOLOGIES, INC.
ATTN: R. SAM NIEDBALA
1745 EATON AVE
BETHLEHEM, PA 18018-1799

510(k) NO: K020371
PHONE NO : 610-882-1820

DEVICE: UPLINK TEST SYSTEM
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ORTHO DEVELOPMENT CORP.
ATTN: CAROL FREASIER
12187 S. BUSINESS PARK DR.
DRAPER, UT 84020

510(k) NO: K020649
PHONE NO : 801-553-9991

DEVICE: ENVISION ANTERIOR CERVICAL PLATE SYSTEM
SE DECISION MADE: 05-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ORTHO-CLINICAL DIAGNOSTICS
AGENT PACK/ CALIBRATORS
ATTN: ANN M QUINN
100 INDIGO CREEK DRIVE
ROCHESTER, NY 14626-5101

510(k) NO: K020662
PHONE NO : 716-453-4041

DEVICE: MODIFICATION TO VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN I RE

SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ORTHOPAEDIC INNOVATIONS, INC.
ATTN: GREGORY M MERCURI
6188 OLSON MEMORIAL HWY.
GOLDEN VALLEY, MN 55422

510(k) NO: K020145
PHONE NO : 763-591-0001

DEVICE: ORTHOPAEDIC INNOVATIONS RENEWAL ACETABULAR CUP SYSTEM
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

OXOID, LTD.
ATTN: A. HOLLINGSWORTH
WADE RD.
BASINGSTOKE, HAMPSHIRE,

510(k) NO: K011710
PHONE NO : 012 568 41144

DEVICE: OXOID PBP2 1 LATEX AGGLUTINATION TEST
SE DECISION MADE: 02-APR-2002
510(k) STATEMENT

PACIFIC CONSOLIDATED INDUSTRIES LL
ATTN: LEE W SMITH
3430 WEST CARRIAGE DRIVE
SANTA ANA, CA 92704

510(k) NO: K020330
PHONE NO : 714-979-9200

DEVICE: DEPLOYABLE OXYGEN CONCENTRATION SYSTEM (DOCS)
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PARAGON VISION SCIENCES
ATTN: WILLIAM E MEYERS
947 EAST IMPALA AVE.
MESA, AZ 85204

510(k) NO: K013310
PHONE NO : 480-507-7606

DEVICE: PVS BASIC 2; EPIC 2
SE DECISION MADE: 25-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PATTON MEDICAL CORP.
ATTN: MICHAEL T PATTON
1000 WESTBANK DRIVE
SUITE 5A200
AUSTIN, TX 78746

510(k) NO: K012279
PHONE NO : 512-329-0469

DEVICE: PATTON TRIPOL
SE DECISION MADE: 30-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

PENTRON LABORATORY TECHNOLOGIES
ATTN: ANNMARIE TENERO
53 NORTH PLAINS INDUSTRIAL RD.
WALLINGFORD, CT 06492-0724

510(k) NO: K020555
PHONE NO : 203-265-7397

DEVICE: SONATA MICRO HYBRID COMPOSITE
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PHILIPS MEDICAL SYSTEMS, INC.
ATTN: SONGHUA ZHANG
3000 MINUTEMAN RD.
ANDOVER, MA 01810-1099

510(k) NO: K020708
PHONE NO : 978-659-7319

DEVICE: PHILIPS PAGEWRITER TOUCH CARDIOGRAPH, MODEL M5000A SERIES
SE DECISION MADE: 25-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PIE MEDICAL
ATTN: COLLEEN DENSMORE
8000 CASTLEWAY DRIVE
INDIANAPOLIS, IN 46250

510(k) NO: K020112
PHONE NO : 317-849-1916

DEVICE: 50S TRINGA ULTRASOUND IMAGING SYSTEM
SE DECISION MADE: 19-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PLEASURE LATEX PRODUCTS SDN. BHD.
ATTN: KOI-YONG LIM
LOT 1365, 17TH MILES, JALAN
SUNGAI SEMBILANG
JERAM, SELANGOR DARUL EHSAN,

510(k) NO: K020272
PHONE NO : 603 326 40784

DEVICE: MALE LATEX CONDOM WITH RIBBED SURFACE
SE DECISION MADE: 26-APR-2002

510(k) STATEMENT

POLYMEDCO, INC.
ATTN: HELEN LANDICHO
510 FURNACE DOCK RD.
CORTLANDT MANOR, NY 10567

510(k) NO: K020532
PHONE NO : 425-814-1514

DEVICE: POLYMEDCO HBA1C TEST
SE DECISION MADE: 24-APR-2002
510(k) STATEMENT

POS-T-VAC, INC.
ATTN: DENNIS L BELL
1701 NORTH 14TH AVE.
DODGE CITY, KS 67801

510(k) NO: K020154
PHONE NO : 800-279-7434

DEVICE: VT-1
SE DECISION MADE: 04-APR-2002
510(k) STATEMENT

POS-T-VAC, INC.
ATTN: DENNIS L BELL
1701 NORTH 14TH AVE.
DODGE CITY, KS 67801

510(k) NO: K020258
PHONE NO : 800-279-7434

DEVICE: SUPPORT SLEEVE
SE DECISION MADE: 04-APR-2002
510(k) STATEMENT

POWER MEDICAL INTERVENTIONS, INC.
ATTN: LAURENCE A POTTER
110 UNION SQUARE DR.
NEW HOPE, PA 18938-1364

510(k) NO: K020343
PHONE NO : 215-862-4450

DEVICE: SURGASSIST SYSTEM; WIRELESS REMOTE CONTROL (COMPONENT); WIRED REMOTE CONTROL
SE DECISION MADE: 10-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PRIMELINE MEDICAL PRODUCTS, INC.
ATTN: BRENDA LEE
10707-100TH AVE., SUITE 300
EDMONTON, ALBERTA,

510(k) NO: K021076
PHONE NO : 780 497 7600 X225

DEVICE: PRIMAGARD YELLOW SURGICAL MASK, PLEATED, TIE-ON, PM4-307; PRIMAGARD YELLOW SURGICAL MASK, PLEATED, EAR-LOOP,PM4-308; PRM
SE DECISION MADE: 16-APR-2002
510(k) STATEMENT

PRISM ENTERPRISES, INC.
ATTN: HOWARD M HOLSTEIN
555 THIRTEENTH STREET N.W.
WASHINGTON, DC 20004-5600

510(k) NO: K020447
PHONE NO : 202-637-5813

DEVICE: MITYVAC MERLIN, MODEL 10027
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PRO-TECH SERVICES, INC.
ATTN: NEIL SHELLER
4338 HARBOUR POINTE BLVD. S.W.
MUKILTEO, WA 98275

510(k) NO: K013905
PHONE NO : 425-481-5452

DEVICE: MODIFICATION EZ-1 SYSTEM REPIRATORY SENSORS
SE DECISION MADE: 22-APR-2002
510(k) STATEMENT

PULPDENT CORPORATION
ATTN: KENNETH J BERK
80 OAKLAND STREET
WATERTOWN, MA 02472

510(k) NO: K020287
PHONE NO : 617-926-6666

DEVICE: DENTITION INTEGRATING MATERIAL
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PULPDENT CORPORATION
ATTN: KENNETH J BERK
80 OAKLAND STREET
WATERTOWN, MA 02472

510(k) NO: K020432
PHONE NO : 617-926-6666

DEVICE: PULPDENT GLAZE
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

PULPDENT CORPORATION
ATTN: KENNETH J BERK
80 OAKLAND STREET
WATERTOWN, MA 02472

510(k) NO: K020481
PHONE NO : 617-926-6666

DEVICE: PULPDENT POST CEMENT
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

QUALITY PRODUCTS OF MONTANA
ATTN: LARRY LARSON
100 NORTH JOHNSON #7
MISSOULA, MT 59801

510(k) NO: K013715
PHONE NO : 406-542-0950

DEVICE: RE-USABLE STERILIZATION POUCH / BAG
SE DECISION MADE: 01-APR-2002
510(k) STATEMENT

QUANTEL MEDICAL
ATTN: ROGER W BARNES
342 SUNSET BAY ROAD
HOT SPRINGS, AR 71913

510(k) NO: K020071
PHONE NO : 501-525-8612

DEVICE: VIRIDIS DERMA LASER
SE DECISION MADE: 05-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

QUANTEL MEDICAL
ATTN: ROGER W BARNES
342 SUNSET BAY ROAD
HOT SPRINGS, AR 71913

510(k) NO: K020072
PHONE NO : 501-525-8612

DEVICE: ATHOS LASER
SE DECISION MADE: 09-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

REPLACEMENT PARTS INDUSTRIES, INC.
ATTN: IRA LAPIDES
P.O. BOX 5019
CHATSWORTH, CA 91313-5019

510(k) NO: K020219
PHONE NO : 818-882-8611

DEVICE: RPI SKIN OR AIR TEMPERATURE PROBE
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

RHIGENE, INC.
ATTN: DAVID KOLESAR
455 STATE ST.,
SUITE 104
DES PLAINES, IL 60068

510(k) NO: K011068
PHONE NO : 847-375-9091

DEVICE: RHIGENE NDNA TEST SYSTEM FOR IMAGETITER, MODEL CL100L
SE DECISION MADE: 11-APR-2002

510(k) STATEMENT

RIGID FX ORTHOPEDICS, INCORPORATED
ATTN: MARK ESTRADA
3601 S. CONGRESS, BLDG B #300
AUSTIN, TX 78704

510(k) NO: K020311
PHONE NO : 512-443-7770

DEVICE: CLEARVIEW WRIST FIXATOR
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ROCHE DIAGNOSTICS CORP.
ATTN: MIKE FLIS
9115 HAGUE RD.
INDIANAPOLIS, IN 46250

510(k) NO: K020740
PHONE NO : 800-428-5074

DEVICE: ROCHE ONLINE THEOPHYLLINE
SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

ROZINN ELECTRONICS, INC.
ATTN: MARK ROSOFF
71-22 MYRTLE AVE.
GLENDALE, NY 11385

510(k) NO: K020213
PHONE NO : 718-386-5526

DEVICE: NETLINK/NETSCAN
SE DECISION MADE: 05-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

RUBICOR MEDICAL, INC.
ATTN: ROBERT J CHIN
25 HARTFORD AVENUE
SAN CAROLS, CA 94070

510(k) NO: K020047
PHONE NO : 650-593-5225

DEVICE: RUBICOR BREAST BIOPSY DEVICE
SE DECISION MADE: 05-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SCANDIA MANUFACTURING LTD.
ATTN: RONALD E BERGLUND
9220 JAMES AVENUE SOUTH
BLOOMINGTON, MN 55431

510(k) NO: K003916
PHONE NO : 612-888-8282

DEVICE: DERMALIFE HYDROFUSION SKIN & BODY CARE SYSTEM
SE DECISION MADE: 15-APR-2002
510(k) STATEMENT

SCHILLER AG
ATTN: MARKUS BUETLER
ALTGASSE 68
BAAR,

510(k) NO: K012226
PHONE NO : 041 766 4252

DEVICE: MONITORING SYSTEM,MODEL ARGUS PB-1000
SE DECISION MADE: 08-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SEAL POLYMER INDUSTRIES SDN. BHD.
WHITE)
ATTN: CHUN CHOOI FONG
LT 72706, JALAN LAHAT, KAWASAN
PERINDUSTRIAN BUKIT MERAH
LAHAT, IPOH, PERAK,

510(k) NO: K020868
PHONE NO : 605 322 3200

DEVICE: CASHMERE NON-STERILE, POWDER FREE NITRILE EXAMINATION GLOVES (
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SMITH & NEPHEW, INC.
ATTN: DEBORAH CONNERS
160 DASCOMB RD.
ANDOVER, MA 01810

510(k) NO: K020947
PHONE NO : 978-749-1495

DEVICE: MODIFICATION TO DYONICS INTELIJET REUSABLE CANNULAS
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SPIRE BIOMEDICAL INC
ATTN: DONALD FICKETT
ONE PATRIOTS PARK
BEDFORD, MA 01730

510(k) NO: K013160
PHONE NO : 781-275-6000

DEVICE: POURCHEZ XPRESSO TWIN LIMEN CHRONIC HEMODIALYSIS CATHETER
SE DECISION MADE: 11-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SSL AMERICA'S, INC.
PRENE SURGEON'S GLOVE
ATTN: JOYCE NING
3585 ENGINEERING DR.,SUITE 200
P.O. BOX 926090
NORCROSS, GA 30092-9214

510(k) NO: K020308
PHONE NO : 770-582-2152

DEVICE: REGENT BIOGEL SKINSENSE STERILE POWDER-FREE, SYNTHETIC POLYISC
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020890
PHONE NO : 952-352-9737

DEVICE: SPYGLASS 4 FR ANGIOGRAPHICY CATHETER
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

STERILMED, INC.
ATTN: PATRICK FLEISCHHACKER
11400 73RD AVE. NORTH
MAPLE GROVE, MN 55369

510(k) NO: K012556
PHONE NO : 888-856-4870

DEVICE: REPROCESSED GUIDEWIRES
SE DECISION MADE: 29-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020629
PHONE NO : 650-949-0470

DEVICE: SIMPLICITY SIMPLEX SOFT INFUSION SET
SE DECISION MADE: 01-APR-2002
510(k) STATEMENT

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

510(k) NO: K020912
PHONE NO : 650-949-0470

DEVICE: SIMPLICITY EASY SOFT INFUSION SET
SE DECISION MADE: 10-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

STERLING MEDIVATIONS, INC. 510(k) NO: K020990
ON OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN
ATTN: JOEL DOUGLAS PHONE NO : 408-297-9474
25285 LA LOMA DR.
LOS ALTOS HILLS, CA 94022-4583

DEVICE: SIMPLICITY SOFT QD II INFUSION SET FOR INFUSION AND/OR INJECTI
SE DECISION MADE: 10-APR-2002
510(k) STATEMENT

STERLING MEDIVATIONS, INC. 510(k) NO: K021005
ECTION OF FLUIDS INTO THE BODY BELOW THE SURFACE
ATTN: JOEL DOUGLAS PHONE NO : 650-814-4083
25285 LA LOMA DR.
LOS ALTOS HILLS, CA 94022-4583

DEVICE: SIMPLICITY EASY ACCESS II INFUSION SET FOR INFUSION AND/OR INJ
SE DECISION MADE: 25-APR-2002
510(k) STATEMENT

STERNGOLD 510(k) NO: K020949
ATTN: MARIA RAO PHONE NO : 508-226-5660
23 FRANK MOSSBERG DR.
ATTLEBORO, MA 02703-0967

DEVICE: APOLLO, MODEL 1124525
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

STETHOGRAPHICS, INC. 510(k) NO: K012387
ATTN: HARVEY KNAUSS PHONE NO : 713-723-4080
11874 S. EVELYN CIRCLE
HOUSTON, TX 77071

DEVICE: STG MULTICHANNEL LUNG SOUND ANALYSIS SYSTEM
SE DECISION MADE: 23-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

STRECK LABORATORIES, INC. 510(k) NO: K020469
ATTN: PAUL KITTELSON PHONE NO : 402-537-5312
7002 SOUTH 109TH ST.
LA VISTA, NE 68128

DEVICE: CAL-CHEX CD PLUS
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SULZER CARBOMEDICS, INC. 510(k) NO: K021051
ATTN: TEFFANY HANKINSON PHONE NO : 512-435-3202
1300 EAST ANDERSON LN.
AUSTIN, TX 78752

DEVICE: ANNULOFLO SYSTEM, MITRAL MODEL AR700
SE DECISION MADE: 23-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SULZER INTRATHERAPEUTICS, INC. 510(k) NO: K020528
ATTN: GLEN D SMYTHE PHONE NO : 651-697-4815
651 CAMPUS DR.
ST. PAUL, MN 55112-3495

DEVICE: INTRASTENT LD (LARGE DIAMETER) STENT
SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SUN BIOMEDICAL LABORATORIES, INC. 510(k) NO: K014089
ATTN: MING SUN PHONE NO : 856-401-1080
604 VPR CENTER
1001 LOWER LANDING RD.
BLACKWOOD, NJ 08012

DEVICE: VISUALINE II (ALSO KNOWN AS SUNLINE) BARITURATES
SE DECISION MADE: 25-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

SURGI-VISION, INC. 510(k) NO: K020495
RNAL MR COIL, AND INTERCEPT VASCULAR INTERNAL MR COIL
ATTN: NANCY E TAYLOR PHONE NO : 301-527-2000
20 FIRSTFIELD RD. SUITE 200
GAITHERSBURG, MD 20878

DEVICE: INTERCEPT ESOPHAGEAL INTERNAL MR COIL, INTERCEPT URETHRAL INTE
SE DECISION MADE: 23-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SUTURA, INC.
0X; MID-LENGTH 06-25-00X
ATTN: JAMES BONDS
17080 NEWHOPE ST.
FOUNTAIN VALLEY, CA 92708

510(k) NO: K020940
PHONE NO : 714-437-9801

DEVICE: SUPERSTITCH VASCULAR SUTURING DEVICE, 6 FRENCH, MODELS 06-15-0
SE DECISION MADE: 17-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SYNTERMED, INC.
ATTN: KENNETH F VAN TRAIN
245 OWENS DRIVE
ANAHEIM, CA 92808

510(k) NO: K020300
PHONE NO : 714-281-1256

DEVICE: NORTHWESTERN GATED BLOOD POOL SPECT (NUMUGAS)
SE DECISION MADE: 23-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: JONATHAN GILBERT
1690 RUSSELL RD.
PAOLI, PA 19301

510(k) NO: K020152
PHONE NO : 610-647-9700

DEVICE: SYNTHES VERTEBRAL SPACER TI
SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020505
PHONE NO : 610-647-9700

DEVICE: SYNTHES TRANSLATING MAXILLARY DISTRACTOR
SE DECISION MADE: 23-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES (USA)
ATTN: VIKKI M HOFFMAN
1690 RUSSELL RD.
PAOLI, PA 19301

510(k) NO: K020517
PHONE NO : 610-647-9700

DEVICE: SYNTHES DUAL-OPENING USS
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SYNTHES SPINE
ATTN: VIKKI M HOFFMAN
1380 ENTERPRISE DRIVE
WEST CHESTER, PA 19380

510(k) NO: K020244
PHONE NO : 610-647-9700

DEVICE: SYNTHES THORACOLUMBAR SPINE LOCKING PLATE (TSLP)
SE DECISION MADE: 22-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

SYSMEX CORPORATION OF AMERICA
EL OF THE SYSMEX SE-9500 AND XE-2100, AUTOMATED HEMATOLOGY
ATTN: NINA GAMPERLING
6699 WILDLIFE WAY
LONG GROVE, IL 60047-9596

510(k) NO: K020496
PHONE NO : 847-726-3675

DEVICE: HPC (HEMATOPOIETIC PROGENITOR CELL) PARAMETER ON THE IMI CHANN
SE DECISION MADE: 12-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TAG MEDICAL PRODUCTS
ATTN: DAN MOOR
KIBBUTZ GAATON,

510(k) NO: K020705
PHONE NO : 011 972 49858400

DEVICE: SIIS#1 TISSUE SUSPENSION SYSTEM
510(k) SUMMARY AVAILABLE FROM FDA

TECHNOLOGY DELIVERY SYSTEMS, INC.
ATTN: DAVID W SCHLERF
200 GREGORY LANE, STE C-100
PLEASANT HILL, CA 94523-3389

510(k) NO: K013300
PHONE NO : 925-356-2640

DEVICE: MAXIFLEX FIBER OPTIC ENERGY DELIVERY SYSTEM
SE DECISION MADE: 16-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TEI BIOSCIENCES INC.
ATTN: KENNETH JAMES
7 ELKINS STREET
BOSTON, MA 02127
510(k) NO: K020455
PHONE NO : 617-268-1616
DEVICE: TISSUEMEND SOFT TISSUE REPAIR MATRIX
SE DECISION MADE: 03-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TERUMO CARDIOVASCULAR SYSTEMS CORP
ATTN: GARRY COURTNEY
125 BLUE BALL ROAD
ELKTON, MD 21921
510(k) NO: K020998
PHONE NO : 800-283-7866
DEVICE: SARNS CENTRIFUGAL PUMP WITH XCOATING, MODEL 164275X
SE DECISION MADE: 04-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

THE KENDALL COMPANY
ATTN: REGINA YEH
15 HAMPSHIRE ST.
MANSFIELD, MA 02048
510(k) NO: K020089
PHONE NO : 508-261-8404
DEVICE: MAHURKAR TRIPLE LUMEN CATHETER, 12 FR
SE DECISION MADE: 10-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TOMEY CORP.
ATTN: MAUREEN O'CONNELL
5 TIMBER LANE
NORTH READING, MA 01864
510(k) NO: K012803
PHONE NO : 978-207-1245
DEVICE: AL-2000 COMBINED BIOMETER AND PACHYMETER
SE DECISION MADE: 08-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TOMEY CORP. USA
ATTN: MAUREEN O'CONNELL
5 TIMBER LANE
NORTH READING, MA 01864
510(k) NO: K020151
PHONE NO : 978-207-1245
DEVICE: UD-1000 ULTRASONIC A/B SCANNER
SE DECISION MADE: 10-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

TRANS VASCULAR INCORPORATED
ATTN: STEVE JWANOUSKOS
1505-D ADAMS DRIVE
MENLO PARK, CA 94925
510(k) NO: K013363
PHONE NO : 650-473-4500
DEVICE: CROSSPOINT TRANSACCESS CATHETER
SE DECISION MADE: 02-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

U-SYSTEMS, INC.
ATTN: SHEILA W PICKERING
2081 LONGDEN CIRCLE
LOS ALTOS,, CA 94204
510(k) NO: K013848
PHONE NO : 650-969-6114
DEVICE: U-SYSTEMS DIAGNOSTIC ULTRASOUND SYSTEM U-2000
SE DECISION MADE: 08-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

UNITED STATES SURGICAL, A DIVISION
ATTN: JENNIFER SCHUCK
150 GLOVER AVE.
NORWALK, CT 06856
510(k) NO: K020134
PHONE NO : 203-845-4512
DEVICE: SPIRAL RADIUS 90-D RODDING SYSTEM
SE DECISION MADE: 15-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

VIBRANT HEALTH
ATTN: STEPHEN EMOND
150 DES GRANDS COTEAUX
BECEIL, QUEBEC,
510(k) NO: K020565
PHONE NO : 450 526 1295
DEVICE: EAV COMBI-2
SE DECISION MADE: 30-APR-2002
510(k) STATEMENT

VIBRANT HEALTH
ATTN: STEPHEN EMOND
150 DES GRANDS COTEAUX
BECEIL, QUEBEC,
510(k) NO: K020568
PHONE NO : 450 526 1295
DEVICE: AKUPORT M-2
SE DECISION MADE: 30-APR-2002
510(k) STATEMENT

VIBRANT HEALTH
ATTN: STEPHEN EMOND
150 DES GRANDS COTEAUX
BELOEIL, QUEBEC,

510(k) NO: K020564
PHONE NO : 450 526 1295

DEVICE: EAV KINDLING 2000S GSR DEVICE
SE DECISION MADE: 30-APR-2002
510(k) STATEMENT

VIVOMETRICS, INC.
ATTN: KEITH GILROY
121 NORTH FIR STREET
SUITE E
VENTURA, CA 93001

510(k) NO: K011903
PHONE NO : 805-667-2225

DEVICE: LIFESHIRT SYSTEM WITH VIVOLOGIC ANALYSIS SOFTWARE
SE DECISION MADE: 12-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

WELL-LIFE HEALTHCARE, INC.
ATTN: TONY C.S. CHANG
NO. 5 ALLEY 5 LANE CHENG HSING
CHUNG CHING RD., PEI TUN DIST.
TAICHUNG,

510(k) NO: K020314
PHONE NO : 886 422 972787

DEVICE: DIGI-PRO TENS, MODEL WL-2204 AND WL-2205
SE DECISION MADE: 30-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

WELL-LIFE HEALTHCARE, INC.
ATTN: TONY C.S. CHANG
NO. 5 ALLEY 5 LANE CHENG HSING
CHUNG CHING RD., PEI TUN DIST.
TAICHUNG,

510(k) NO: K021359
PHONE NO : 886 422 972476

DEVICE: DIGI-PRO TENS MODEL WL-2203 AND WL-2205
SE DECISION MADE: 30-APR-2002

510(k) SUMMARY AVAILABLE FROM FDA

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

510(k) NO: K020347
PHONE NO : 49 723 13705219

DEVICE: AGC SPEZIALLEGIERUNG
SE DECISION MADE: 24-APR-2002
510(k) SUMMARY AVAILABLE FROM FDA

WISAP GESELLSCHAFT FUR WISSENSCHAF
ATTN: HORST SEMM
RUDOLF-DIESEL-RING 20
SAUERLACH,

510(k) NO: K011510
PHONE NO : 490 810 489080

DEVICE: MULTI HI-FLO PNEU, WISAP #7080
SE DECISION MADE: 02-APR-2002
510(k) STATEMENT

Z7 INTERNATIONAL
ATTN: PHIL ZULUETA
34138 COURTNEY TERRACE
ACTON, CA 93510

510(k) NO: K021048
PHONE NO : 661-269-1006

DEVICE: THERMOMETER MODELS ST8631
SE DECISION MADE: 22-APR-2002
510(k) STATEMENT

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

510(k) NO: K021103

PHONE NO : 908-526-3744

DEVICE: MODIFICATION TO ZEUS SCIENTIFIC'S ATHENA MULTI-LYTE ANA TEST S

SE DECISION MADE: 24-APR-2002
510(k) STATEMENT

ZOLL MEDICAL CORP.
ATTN: PAUL DIAS
32 SECOND AVENUE
BURLINGTON, MA 01803-4420

510(k) NO: K011541
PHONE NO : 800-242-9150

DEVICE: ZOLL PAD WITH CPR AID
SE DECISION MADE: 11-APR-2002
510(k) STATEMENT