

JANUARY 2002

SUBMITTER ADDRESS LISTING FOR CDPH SUBSTANTIALLY EQUIVALENT 510(K) SUMMARIES OR 510(K) STATEMENTS  
FOR FINAL DECISIONS RENDERED DURING THE PERIOD U. JAN-2002 THROUGH 31-JAN-2002

05-FEB-2002  
Page 1

*Rec'd 2/6/02*

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

510(k) NO: K013535  
PHONE NO : 410-580-1730

DEVICE: EVTOOL MODEL # V. 1.0  
SE DECISION MADE: 18-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

3D SHARP, INC.  
ATTN: DONALD KRIEGER  
6425 FORWARD AVE.  
PITTSBURGH, PA 15217

510(k) NO: K013841  
PHONE NO : 412-648-9211

DEVICE: 3DFIS, MODEL IES-FL-101  
SE DECISION MADE: 17-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

ADVANCED CARDIOVASCULAR SYSTEMS,  
HILIC COATING  
ATTN: JOANNA MROZ  
3200 LAKESIDE DRIVE  
SANTA CLARA, CA 95052-8167

510(k) NO: K012534  
PHONE NO : 408-845-3956

DEVICE: HI-TORQUE MIDDLE SUPPORT .012 GUIDE WIRE WITH HYDROCOAT HYDROF  
SE DECISION MADE: 24-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

AIRSEP CORP.  
ATTN: CHARLOTTE H HAMILTON  
290 CREEKSLIDE DR.  
BUFFALO, NY 14228-2070

510(k) NO: K012037  
PHONE NO : 716-691-0202

DEVICE: HEALTHLIFE OXYGEN CONCENTRATOR MODEL AS009  
SE DECISION MADE: 17-JAN-2002  
510(k) STATEMENT

ALLTRACEL PHARMA LTD.  
ATTN: CHARLES H KYPER  
103 NOLEN LANE  
CHAPEL HILL, NC 27516

510(k) NO: K010933  
PHONE NO : 919-960-0049

DEVICE: SEAL-ON TOPICAL HEMPSTATIC POWDER SPRAY  
SE DECISION MADE: 08-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

AMERICAN LABORATORY PRODUCTS CO.,  
ATTN: RICHARD E CONLEY  
P.O. BOX 451  
WINDHAM, NH 03087

510(k) NO: K012576  
PHONE NO : 603-893-8914

DEVICE: CIC-C1Q EIA  
SE DECISION MADE: 29-JAN-2002  
510(k) STATEMENT

APEX MEDICAL CORP.  
ATTN: ALAN CHANG  
10TH FL., NO. 31, LANE 169,  
KANG NING ST.  
SHI-CHIH, TAIPEI HSIEN,

510(k) NO: K020032  
PHONE NO : 886 226 954170

DEVICE: APEX MEDICAL MINI TENS  
SE DECISION MADE: 31-JAN-2002  
510(k) STATEMENT

APPLIED MEDICAL RESOURCES CORP.  
ATTN: ANIL BHALANI  
22872 AVENIDA EMPRESSA  
RANCHO SANTA MARGARITA, CA 92688

510(k) NO: K012884  
PHONE NO : 949-713-8000

DEVICE: DILATING TIP OBTURATOR  
SE DECISION MADE: 17-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

ARTHROCARE CORP.  
ATTN: BRUCE PROTHRO  
595 NORTH PASTORIA AVE.  
SUNNYVALE, CA 94085-2936

510(k) NO: K014222  
PHONE NO : 408-736-0224

DEVICE: ARTHROCARE CONTROLLER, PATIENT CABLE, FOOT CONTROL, POWER CORD  
SE DECISION MADE: 18-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

945-0120

LST 111

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

05-FEB-2002  
Page 2

ATRIUM MEDICAL CORP. ATTN: JOSEPH P PAOLO 5 WENTWORTH DR. HUDSON, NH 03051	510(k) NO: K013577 PHONE NO : 603-880-1433	DEVICE: ULTRAMAX WOVEN VELOUR VASCULAR GRAFT SE DECISION MADE: 25-JAN-2002 510(k) STATEMENT
AUGUSTINE MEDICAL, INC. XX ATTN: SCOTT D AUGUSTINE 10393 WEST 70TH ST. EDEN PRAIRIE, MN 55344	510(k) NO: K020077 PHONE NO : 952-947-1200	DEVICE: MODIFICATION TO AUGUSTINE MEDICAL WOUND CARE SYSTEM, MODEL 68X SE DECISION MADE: 31-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
AVANTA ORTHOPAEDICS, INC. ATTN: LOUISE M FOCHT 9369 CARROLL PARK DRIVE, STE.A SAN DIEGO, CA 92121	510(k) NO: K013629 PHONE NO : 858-452-8580	DEVICE: FINGER JOINT PROSTHESIS SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
B. BRAUN MEDICAL, INC. ATTN: SHERI L MUSGNUNG 901 MARCON BLVD. ALLENTOWN, PA 18109	510(k) NO: K013610 PHONE NO : 610-266-0500	DEVICE: PERIFIX SAFETY EPIDURAL NEEDLES SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BARCO NV ATTN: FRANK FERGUSON P.O. BOX 12038 LA JOLLA, CA 92039-2038	510(k) NO: K013922 PHONE NO : 858-587-1147	DEVICE: CORONIS 3MP MEDICAL FLAT PANEL DISPLAY SYSTEM SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYER DIAGNOSTICS CORP. ATTN: KENNETH T EDDS 511 BENEDICT AVE TARRYTOWN, NY 10591-5097	510(k) NO: K013750 PHONE NO : 914-524-2446	DEVICE: ADVIA 1650 CHOLINESTERASE ASSAY SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BAYER DIAGNOSTICS CORP. ALYZERS ATTN: KENNETH T EDDS 511 BENEDICT AVE TARRYTOWN, NY 10591-5097	510(k) NO: K013959 PHONE NO : 914-524-2446	DEVICE: BAYER VALPROIC ACID ASSAY FOR THE ACS:180 AND ADVIA CENTAUR AN SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BCI, INC. ATTN: DONALD ALEXANDER N7 W22025 JOHNSON ROAD WAUKESHA, WI 53186	510(k) NO: K013171 PHONE NO : 262-542-3100	DEVICE: 3420 DIGIT PULSE OXIMETER, MODEL 3420 SE DECISION MADE: 03-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BD TION, USP SYRINGE ATTN: GREGORY W MORGAN 1 BECTON DR. MC 226 FRANKLIN LAKES, NJ 07417	510(k) NO: K011967 PHONE NO : 201-847-4344	DEVICE: BD PRE-FILLED HEPARIN LOCK FLUSH IN 0.9% SODIUM CHLORIDE INJEC SE DECISION MADE: 23-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

BECKMAN COULTER, INC. ATTN: MARY BETH TANG 200 SOUTH KRAEMER BLVD.,W-104 P.O. BOX 8000 BREA, CA 92822-8000	510(k) NO: K013978 PHONE NO : 714-961-3777	DEVICE: SYNCHRON SYSTEMS PANCREATIC AMYLASE (PAM) REAGENT SE DECISION MADE: 15-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
BECKMAN COULTER, INC.  ATTN: MARY BETH TANG 200 SOUTH KRAEMER BLVD.,W-104 BREA, CA 92822-8000	510(k) NO: K014103  PHONE NO : 714-961-3777	DEVICE: SYNCHRON SYSTEMS DIRECT LDL CHLOESTEROL REAGENT AND CALIBRATOR  SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BECTON DICKINSON INFUSION THERAPY LDED INTRODUCER ATTN: LESLIE WOOD 9450 SOUTH STATE ST. SANDY, UT 84070	510(k) NO: K013304  PHONE NO : 801-565-2504	DEVICE: BD INTROSYTE PRECISION INTRODUCER, BD INTROSYTE AUTOGAURD SHIE  SE DECISION MADE: 02-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOCARDIA, INC. ATTN: DANIEL C ROSENMAN 384 OYSTER POINT BLVD. #6 SOUTH SAN FRANCISCO, CA 94080	510(k) NO: K012749 PHONE NO : 650-624-0120	DEVICE: BIOCARDIA UNIVERSAL DEFLECTABLE GUIDE CATHETER, MODEL 000664 SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOCHECK, INC. ATTN: ROBIN J HELLEN 9418 LASAINE AVE NORTHBRIDGE, CA 91325	510(k) NO: K013062 PHONE NO : 818-709-5646	DEVICE: BIOCHECK HUMAN CARDIAC TROPONIN-I IMMUNOASSAY TEST KIT SE DECISION MADE: 08-JAN-2002 510(k) STATEMENT
BIOFORM, INC. 8021-1, 0008022-1 ATTN: VICTOR M BOWERS 4133 COURINEY ROAD, #10 FRANKSVILLE, WI 53126	510(k) NO: K013243  PHONE NO : 262-835-9800	DEVICE: COAPTITE LARYNGEAL AUGMENTATION SYSTEM 1CC & 0.5CC, MODELS 000  SE DECISION MADE: 09-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOHORIZONS IMPLANT SYSTEMS, INC. ATTN: DONALD E DALTON ONE PERIMETER PARK SOUTH SUITE 230, SOUTH BIRMINGHAM, AL 35243	510(k) NO: K020133 PHONE NO : 205-967-7880	DEVICE: MODIFICATION TO THE MAESTRO SYSTEM SE DECISION MADE: 25-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
BIOLASE TECHNOLOGY, INC. ATTN: IOANA M RIZOIU 981 CALLE AMANECEER SAN CLEMENTE, CA 92673	510(k) NO: K012511 PHONE NO : 949-361-1200	DEVICE: WATERLASE MILLENNIUM SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOLIGHT INTERNATIONAL AB ATTN: CONSTANCE G BUNDY 6740 RIVERVIEW TERRACE MINNEAPOLIS, MN 55432	510(k) NO: K011355 PHONE NO : 763-574-1976	DEVICE: BIOLIGHT PCD SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALEN. 510(K) SUMMARIES OR 510(K) STATEMENTS  
FOR FINAL DECISIONS RENDERED DURING THE PERIOD JAN-2002 THROUGH 31-JAN-2002

05-FEB-2002  
Page 4

BIOMEDICAL IMPLANT TECHNOLOGY, INC ATTN: RODNEY J SHAUGHNESSY 206 KING ST. ST. CATHERINES, ONTARIO,	510(k) NO: K013383 PHONE NO : 514 631 2649	DEVICE: BICHEX ONE-PIECE ONE STAGE DENTAL IMPLANT SYSTEM SE DECISION MADE: 10-JAN-2002 510(k) STATEMENT
BIOMET ORTHOPEDICS, , INC. ATTN: DALENE T BINKLEY P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K020045 PHONE NO : 219-267-6639	DEVICE: 3-PIECE PROXIMAL HUMERAL REPLACEMENT SYSTEM SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET ORTHOPEDICS, , INC. ATTN: TRACY J BICKEL P.O. BOX 587 WARSAW, IN 46581-0587	510(k) NO: K020076 PHONE NO : 219-267-6639	DEVICE: PATRIOT PROTRUSIO CAGE SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BIOMET, INC. ATTN: PATRICIA SANDBORN BERES 56 EAST BELL P.O. BOX 587 WARSAW, IN 46582	510(k) NO: K012551 PHONE NO : 219-267-6639	DEVICE: LIVERPOOL RADIAL HEAD REPLACEMENT DEVICE SE DECISION MADE: 30-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
BIOSITE DIAGNOSTICS ATTN: JEFFREY R DAHLEN 11030 ROSELLE ST. SAN DIEGO, CA 92121	510(k) NO: K012745 PHONE NO : 858-455-4808	DEVICE: TRIAGE TOX DRUG SCREEN, CATALOG #94000 SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BISCO, INC. ATTN: STEPHEN D SMITH 1100 WEST IRVING PARK RD. SCHAUMBURG, IL 60193	510(k) NO: K013519 PHONE NO : 847-534-6146	DEVICE: SIMPLE SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BLACKSTONE MEDICAL, INC. ATTN: ALAN LOMBARDO 90 BROOKSDALE DR. SPRINGFIELD, MA 01104	510(k) NO: K012184 PHONE NO : 973-633-9968	DEVICE: BLACKSTONE III ANTERIOR CERVICAL PLATING SYSTEM SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BLACKSTONE MEDICAL, INC. ATTN: ALAN LOMBARDO 90 BROOKSDALE DR. SPRINGFIELD, MA 01104	510(k) NO: K013558 PHONE NO : 973-633-9968	DEVICE: BLACKSTONE SPINAL FIXATION SYSTEM 4.5MM MONO-AXIAL SCREW SE DECISION MADE: 23-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOEHRINGER LABORATORIES ATTN: JOHN KARPOWICZ 500 E. WASHINGTON STREET NORRISTOWN, PA 19401	510(k) NO: K013976 PHONE NO : 610-278-0900	DEVICE: BOEHRINGER MRI SUCTION REGULATORY SE DECISION MADE: 08-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 5

BOSTON SCIENTIFIC MACH1/34358-XXX ATTN: TODD KORNMANN ONE SCIMED PLACE MAPLE GROVE, MN 55311	510(k) NO: K020028 PHONE NO : 763-694-5857	DEVICE: 6F MACH1/34356-XXX; 5F MACH1/35845-XXX; 7F MACH1/34357-XXX; 8F SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC, TARGET ATTN: SETH A SCHULMAN 47900 BAYSIDE PARKWAY FREMONT, CA 94538	510(k) NO: K012985 PHONE NO : 510-440-7753	DEVICE: MATRIX DETACHABLE COILS SE DECISION MADE: 31-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BOSTON SCIENTIFIC/MEDI-TECH ATTN: JODI L GREENIZEN ONE BOSTON SCIENTIFIC PLACE NATICK, MA 01760-1537	510(k) NO: K020012 PHONE NO : 518-742-4338	DEVICE: MODIFICATION TO RENEGADE FIBER BRAIDED MICROCATETER SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
BSN-JOBST, INC. ATTN: ANGELO R PEREIRA 5825 CARNEGIE BLVD. CHARLOTTE, NC 28209-4633	510(k) NO: K013852 PHONE NO : 704-551-7178	DEVICE: JOBST READY-TO-WEAR GAUNTLET SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. AND TEMPLINK M EXTENSION CABLES ATTN: EBORAH L HERRINGTON 55 TECHNOLOGY DR. LOWELL, MA 01851	510(k) NO: K013598 PHONE NO : 978-323-2216	DEVICE: REUSE CLAIM FOR THE BARD ELECTROPHYSIOLOGY SURELINK, TEMPLINK, SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
C.R. BARD, INC. ATTN: CAROL VIERLING 13183 HARLAND DR. COVINGTON, GA 30014	510(k) NO: K014212 PHONE NO : 770-385-2347	DEVICE: BARD CONQUEST PTA BALLOON DILATATION CATHETER SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CANON U.S.A., INC. ATTN: SHEILA DRISCOLL ONE CANON PLAZA LAKE SUCCESS, NY 11042-1198	510(k) NO: K003689 PHONE NO : 516-328-5602	DEVICE: CANON X-RAY DIGITAL CAMERA, MODEL CXDI-31 SE DECISION MADE: 02-JAN-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: K013354 PHONE NO : 250 744 1822	DEVICE: GLOBALCARDIO SE DECISION MADE: 31-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CARL ZEISS OPHTHALMIC SYSTEMS, INC ATTN: MELISSA R HORNE 5160 HACIENDA DR. DUBLIN, CA 94568	510(k) NO: K012727 PHONE NO : 925-557-4100	DEVICE: HUMPHREY OCT3 SE DECISION MADE: 31-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 6

CARTER-WALLACE, INC. ATTN: MAUREEN GARNER P.O. BOX 1001 HALF ACRE ROAD CRANBURY, NJ 08512	510(k) NO: K011855 PHONE NO : 609-655-6345	DEVICE: WAMPOLE HS-CRP ELISA SE DECISION MADE: 08-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
CATHEFFECTS, LLC. ATTN: SHAWN FOJTIK 1100 MELODY LANE; SUITE 108 ROSEVILLE, CA 95678	510(k) NO: K012089 PHONE NO : 916-677-1790	DEVICE: CATHEFFECTS' DESAI VECTORCATH MAPPING SYSTEM SE DECISION MADE: 28-JAN-2002 510(k) STATEMENT
CHURCHILL MEDICAL SYSTEMS, INC. ATTN: KEITH PALUCH 87 VENTURE DR. DOVER, NH 03820	510(k) NO: K013950 PHONE NO : 603-743-5988	DEVICE: VENTED VIAL ACCESS DEVICE SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILALE FROM FDA
CIRCON ACMI ATTN: WAYNE B STERNER 300 STILLWATER AVE. P.O. BOX 1971 STAMFORD, CT 06904-1971	510(k) NO: K013165 PHONE NO : 805-961-3290	DEVICE: USA SERIES LAPAROSCOPES SE DECISION MADE: 18-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
CIRCON VIDEO ATTN: JOHN DELUCIA 492 OLD CONNECTICUT PATH FRAMINGHAM, MA 01701-4584	510(k) NO: K011876 PHONE NO : 508-879-4835	DEVICE: DOLPHIN II FLUID MANAGEMENT SYSTEM, MODEL DOL-2 SE DECISION MADE: 08-JAN-2002 510(k) STATEMENT
COALESCENT SURGICAL ATTN: MICHAEL A DANIEL 559 EAST WEDDELL DR. SUNNYVALE, CA 94089	510(k) NO: K013664 PHONE NO : 415-407-0223	DEVICE: COALESCENT SURGICAL U-CLIP SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CONFIDENT TECHNOLOGY, INC. ATTN: LEWIS LIN 13841 ROSWELL AVE. # K CHINO, CA 91710	510(k) NO: K013690 PHONE NO : 909-590-8665	DEVICE: IDENT-A100 INTRACORAL VIDEO CAMERA SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CONFIRMA ATTN: CHERYL SHEA 821 KIRKLAND AVENUE KIRKLAND, WA 98033	510(k) NO: K013574 PHONE NO : 425-576-3247	DEVICE: ACCENT SE DECISION MADE: 15-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CONTINUUM ELECTRO-OPTICS, INC. -SWITCHED ND: YAG LASER ATTN: RONALD KOHLHARDT 3150 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051	510(k) NO: K014234 PHONE NO : 408-727-3240	DEVICE: MEDLITE IV Q-SWITCHEDND: YAGLASER REPLACED BY THE MEDLITE C6 Q  SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 7

COSMO HEALTH, INC. ATTN: ROBERT SCHLIFF 1129 BLOOMFIELD AVE. WEST CALDWELL, NJ 07006	510(k) NO: K013507 PHONE NO : 973-227-1830	DEVICE: COSMO'S COSMO TENS PF-990 MINI DIGITAL WIRELESS MESSAGE PATCH SE DECISION MADE: 25-JAN-2002 510(k) STATEMENT
CP MEDICAL S ATTN: MARY ANN GREENWALT P.O. BOX 6724 PORTLAND, OR 97208	510(k) NO: K013964 PHONE NO : 503-232-1555	DEVICE: MODIFICATION TO ACCU-SPACE PLAIN GUT ABSORBABLE SEEDING SPACER SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CRANIAL TECHNOLOGIES, INC. ATTN: TIMOTHY R LITTLEFIELD 1395 WEST AUTO DR. TEMPE, AZ 85284	510(k) NO: K014012 PHONE NO : 480-505-1840	DEVICE: DOC BAND SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
CROSSTEX INTL. UID EARLOOP FACE MASKS-BLUE, PINK, WHITE, GREEN. CROSSTEX ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD., SUITE 200 GREAT NECK, NY 11021	510(k) NO: K012602 PHONE NO : 516-482-9001	DEVICE: CROSSTEX ISOLITE EARLOOP FACE MASKS-BLUE, PINK, CROSSTEX ISOFL SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: REBECCA S AYASH GLASGOW SITE P.O. BOX 6101 NEWARK, DE 19714	510(k) NO: K013128 PHONE NO : 302-631-6276	DEVICE: N LATEX LP(A) SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DADE BEHRING, INC. ATTN: RADAMES RIESGO 13251 NW 9TH TERRACE MIAMI, FL 33182	510(k) NO: K013155 PHONE NO : 305-480-7558	DEVICE: DADE THROMBOPLASTIN C PLUS SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DATEX-OHMEDA ATTN: JOEL KENT 86 PILGRIM ROAD NEEDHAM, MA 02492	510(k) NO: K013387 PHONE NO : 781-449-8685	DEVICE: DATEX-OHMEDA S/5 WEB VIEWER SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DATEX-OHMEDA ATTN: JOEL KENT 86 PILGRIM ROAD NEEDHAM, MA 02492	510(k) NO: K013389 PHONE NO : 781-449-8685	DEVICE: DATEX-OHMEDA S/5 BIS MODULE, M-BIS AND ACCESSORIES SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DATEX-OHMEDA, INC. ATTN: BILL EXNER P.O. BOX 7550 MADISON, WI 53707-7550	510(k) NO: K012924 PHONE NO : 608-221-1551	DEVICE: DATEX-OHMEDA TEC 7 ANESTHESIA VAPORIZER SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA



SUBMITTER ADDRESS LISTING FOR CDH SUBSTANTIALLY EQUIVALEN. 510(K) SUMMARIES OR 510(K) STATEMENTS  
FOR FINAL DECISIONS RENDERED DURING THE PERIOD U. JAN-2002 THROUGH 31-JAN-2002

05-FEB-2002  
Page 8

DELDENT LTD. ATTN: ALAN EDEL 19 KEREN KAYEMET STREET PETACH TIKVAH,	510(k) NO: K013969 PHONE NO : 723-921-1492	DEVICE: MINIBLASTER SE DECISION MADE: 10-JAN-2002 510(k) STATEMENT
DELDENT LTD. ATTN: ALAN EDEL 19 KEREN KAYEMET STREET PETACH TIKVAH,	510(k) NO: K014238 PHONE NO : 972 3 9049668	DEVICE: DELSONIC 2000 SE DECISION MADE: 24-JAN-2002 510(k) STATEMENT
DELDENT LTD. ATTN: ALAN EDEL 19 KEREN KAYEMET STREET PETACH TIKVAH,	510(k) NO: K014245 PHONE NO : 972 3 9049668	DEVICE: JETSONIC 2000 SE DECISION MADE: 29-JAN-2002 510(k) STATEMENT
DENTAL IMAGINEERS & ASSOCIATES ATTN: WILLIAM A BELFER 804 WEST PARK AVE. OCEAN, NJ 07712	510(k) NO: K013808 PHONE NO : 732-493-4747	DEVICE: SLEEPBITE SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DENTAL MANUFACTURING S.P.A TONE PREFORMED PLASTIC DENTURE TEETH ATTN: KEVIN WALLS 13 RED FOX LANE LITTLETON, CO 80127	510(k) NO: K013824 PHONE NO : 720-962-5412	DEVICE: ACRY PLUS, ACRY LUX, ACRY LUX V, ACRY ROCK, ACRY ROCK V AND Z- SE DECISION MADE: 30-JAN-2002 510(k) STATEMENT
DENTAL SYSTEMS.COM, INC. ATTN: SHINOBU DOI 1187 TADSWORTH TERRACE HEATHROW, FL 32746	510(k) NO: K020171 PHONE NO : 407-927-4302	DEVICE: COOLELU2 DENTAL RESIN CURING DEVICE SE DECISION MADE: 29-JAN-2002 510(k) STATEMENT
DEPUY ORTHOPAEDICS, INC. ATTN: LYNNETTE WHITAKER 700 ORTHOPAEDIC DR. P.O. BOX 988 WARSAW, IN 46581-0988	510(k) NO: K011533 PHONE NO : 219-371-4903	DEVICE: DEPUY FEMORAL HEADS SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DI-CHEM, INC. ATTN: KEITH A BUCHHOLZ 12297 ENSIGN AVE. NORTH CHAMPLIN, MN 55316	510(k) NO: K012328 PHONE NO : 800-847-2598	DEVICE: HEMO-LYTE HEMODIALYSIS GRADE SODIUM BICARBONATE POWDER SE DECISION MADE: 18-JAN-2002 510(k) STATEMENT
DI-CHEM, INC. ATTN: KEITH A BUCHHOLZ 12297 ENSIGN AVE. NORTH CHAMPLIN, MN 55316	510(k) NO: K012547 PHONE NO : 800-847-2598	DEVICE: HEMO-LYTE HEMODIALYSIS GRADE SODIUM BICARBONATE SOLUTION SE DECISION MADE: 18-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 9

DIABETES TECHNOLOGIES, INC. ATTN: ARTHUR G WILLIAMS 216 WEST JACKSON ST. THOMASVILLE, GA 31792	510(k) NO: K013465 PHONE NO : 229-227-1245	DEVICE: ACCU-BASE HEMOGLOBIN A1C SAMPLE COLLECTION KIT SE DECISION MADE: 22-JAN-2002 510(k) STATEMENT
DIAGNOSTIC PRODUCTS CORP. TOXOPLASMA IGM, MODEL L2KTM2 AND L2KTM6 ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K012075 PHONE NO : 310-645-8200	DEVICE: IMMULITE TOXOPLASMA IGM, MODEL LKTM1 AND LKTM2, IMMULITE 2000 SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIAGNOSTIC PRODUCTS CORP. MODEL L2KRM2, L2KRM6 ATTN: EDWARD M LEVINE 5700 WEST 96TH ST. LOS ANGELES, CA 90045	510(k) NO: K012077 PHONE NO : 310-645-8200	DEVICE: IMMULITE RUBELLA IGM,LKRM1, LKRM2, IMMULITE 2000 RUBELLA IGM, SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIAMEDIX CORP. ATTN: LYNNE STIRLING 2140 NORTH MIAMI AVE. MIAMI, FL 33127	510(k) NO: K013956 PHONE NO : 305-324-2300	DEVICE: DIAMEDIX IS-ANTI-B2 GLYCOPROTEIN I SCREEN SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIAMETRICS MEDICAL, INC. ATTN: NANCY RING 2658 PATTON RD. ROSEVILLE, MN 55113	510(k) NO: K013938 PHONE NO : 651-638-1250	DEVICE: IRMA SL BLOOD ANALYSIS SYSTEM LACTATE CARTRIDGE SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIDECO S.P.A. ATTN: BARRY S SALL 195 WEST STREET WALTHAM, MA 02451-1163	510(k) NO: K014080 PHONE NO : 781-434-4742	DEVICE: APEX ADULT HOLLOWE FIBER OXYGENATOR SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DIOMED, LTD. ATTN: MAUREEN O'CONNELL 5 TIMBER LANE NORTH READING, MA 01864	510(k) NO: K012398 PHONE NO : 978-207-1245	DEVICE: DIOMED 15 DIODE LASER SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DMG USA, INC. ATTN: PAMELA PAPINEAU 5 WHITCOMB AVENUE AYER, MA 01432	510(k) NO: K013571 PHONE NO : 978-772-3552	DEVICE: MAGICFIL SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DMG USA, INC. ATTN: PAMELA PAPINEAU 5 WHITCOMB AVENUE AYER, MA 01432	510(k) NO: K013674 PHONE NO : 978-772-3552	DEVICE: LUXATEMP/LUXATEMP SOLAR/INSTATEMP SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 10

DOCTOR'S RESEARCH GROUP, INC. ATTN: RICHARD DESLAURIES 143 WOLCOTT RD. WOLCOTT, CT 06716	510(k) NO: K011736 PHONE NO : 203-879-9422	DEVICE: DRG QUICKMIX SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DOXA CERTEK AB 6B, AND 6C ATTN: JONATHAN S KAHAN 555 13TH STREET N.W. WASHINGTON, DC 20004-1109	510(k) NO: K011839 PHONE NO : 202-637-5600	DEVICE: DOXADENT DENTAL COMPOSITE, MODELS A, B, C, 12A, 12B, 12C, 6A, SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DRAEGER MEDICAL, INC. ATTN: JAMES J BRENNAN 3135 QUARRY RD. TELFORD, PA 18969	510(k) NO: K012139 PHONE NO : 215-721-5400	DEVICE: VAMOS ANESTHETIC GAS MONITOR SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
DYNAMIC TECHNOLOGY CORP. 0 HFS, POLYSULFONE 130 HFS ATTN: YAW C YANG SCIENCE-BASED INDUSTRIAL PARK HSINCHU,	510(k) NO: K011537 PHONE NO : 886 357 89566	DEVICE: DYNAMIC HOLLOW FIBER DIALYZER DS-SERIES, MODEL: POLYSULFONE 10 SE DECISION MADE: 07-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: FREDERIC TESTA 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K014137 PHONE NO : 973-299-9300	DEVICE: MODIFICATION TO EBI OMEGA 21 SYSTEM SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
EBI, L.P. ATTN: PATRICIA M FLOOD 100 INTERPACE PKWY. PARSIPPANY, NJ 07054-1079	510(k) NO: K014194 PHONE NO : 973-299-9300	DEVICE: MODIFICATION TO EBI XFIX VISION FIXATION SYSTEM SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
EMT-RX ATTN: ROBERT J BARD 9400 RANDELL RD., SUITE 10 RALEIGH, NC 27603	510(k) NO: K002142 PHONE NO : 919-552-9689	DEVICE: SALINE IV FLUSH SYRINGE SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENCORE ORTHOPEDICS, INC. ATTN: JOANNA DROEGE 9800 METRIC BLVD. AUSTIN, TX 78758	510(k) NO: K013442 PHONE NO : 512-832-9500	DEVICE: PASS SPINAL SYSTEM SE DECISION MADE: 15-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENCORE ORTHOPEDICS, INC. ATTN: JOANNA DROEGE 9800 METRIC BLVD. AUSTIN, TX 78758	510(k) NO: K013490 PHONE NO : 512-832-9500	DEVICE: CEMENTED CALCAR HIP SYSTEM SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 11

ENDOCARE, INC. ATTN: VINCENT CUTARTELLI 7 STUDEBAKER IRVINE, CA 92618	510(k) NO: K011074 PHONE NO : 949-595-4770	DEVICE: CRYOCARE SURGICAL SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ENDOTEC, INC. MODEL 1 ATTN: ALEX CANONACO 20 VALLEY STREET SOUTH ORANGE, NJ 07079	510(k) NO: K012702 PHONE NO : 973-762-0095	DEVICE: BUECHEL-PAPPAS (B-P) FIXED BEARING NEW JERSEY (NJ) TOTAL KNEE, SE DECISION MADE: 30-JAN-2002 510(k) STATEMENT
EPITEEST LTD. OY ATTN: CLAWSON BOWMAN 1330A REDWOOD WAY PETALUMA, CA 94954-1169	510(k) NO: K013820 PHONE NO : 707-793-2600	DEVICE: FINN CHAMBER (R) SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ETHICON ENDO-SURGERY, INC. ATTN: DOUG KENTZ 4545 CREEK RD. CINCINNATI, OH 45242-2839	510(k) NO: K013576 PHONE NO : 513-337-8699	DEVICE: PERICSCOPE, MODEL # PERISC1 SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
EVER-SAFETY TECHNICAL SERVICE ATTN: DANIEL YANG NO 13 ALLEY 28 LANE 108 YOUNG FENG RD TAICHUNG HSIEN, TAIWAN,	510(k) NO: K013116 PHONE NO :	DEVICE: DURO/ QUALIDURA SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
EXELINT INTL. CO. ATTN: ARMAND HAMID P.O. BOX 3194 CULVER CITY, CA 90231-3194	510(k) NO: K011757 PHONE NO : 310-649-0707	DEVICE: EXEL COMFORTPOINT INSULIN PEN NEEDLE SE DECISION MADE: 23-JAN-2002 510(k) STATEMENT
EXELINT INTL. CO. ATTN: ARMAND HAMID 5840 WEST CENTINELA AVE. LOS ANGELES, CA 90045	510(k) NO: K012879 PHONE NO : 310-649-0707	DEVICE: EXEL HUBER INFUSION SET WITH NEEDLELESS INJECTION SITE SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
GALIL MEDICAL LTD. ATTN: JONATHAN S KAHAN 555 THIRTEEN ST., N.W. WASHINGTON, DC 20009	510(k) NO: K011950 PHONE NO : 202-637-5794	DEVICE: SEEDNET, MODEL FP6T5, FP5T5, FP5T3 SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
GAMBRO RENAL PRODUCTS ATTN: FEI LAW 1845 MASON AVE. DAYTONA BEACH, FL 32117-5102	510(k) NO: K013448 PHONE NO : 386-274-2811	DEVICE: PRISMASATE SE DECISION MADE: 15-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 12

GAMBRO RENAL PRODUCTS  
ATTN: FEI LAW  
1845 MASON AVE.  
DAYTONA BEACH, FL 32117-5102

510(k) NO: K013724  
PHONE NO : 386-274-2811

DEVICE: BICART  
SE DECISION MADE: 08-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GE MEDICAL SYSTEMS  
ATTN: LARRY A KROGER  
P.O. BOX 414  
MILWAUKEE, WI 53201

510(k) NO: K013636  
PHONE NO : 262-544-3894

DEVICE: SIGNA INFINITY MAGNETIC RESONANCE SYSTEM  
SE DECISION MADE: 24-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GE MEDICAL SYSTEMS  
ATTN: ALLEN SCHUH  
P.O. 414  
MILWAUKEE, WI 53201

510(k) NO: K014097  
PHONE NO : 414-647-4385

DEVICE: GE LOGIQ 5  
SE DECISION MADE: 10-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GENERAL DEVICES  
ATTN: MICHAEL SMITH  
1000 RIVER ST.  
RIDGEFIELD, NJ 07657

510(k) NO: K013533  
PHONE NO : 201-313-7075

DEVICE: EMS TELEMEDICINE OPTION (FOR GEMS SERIES 4000)  
SE DECISION MADE: 18-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GENERAL ELECTRIC CO.  
ATTN: ALLEN SCHUH  
P.O. BOX 414  
MILWAUKEE, WI 53201

510(k) NO: K014206  
PHONE NO : 414-647-4385

DEVICE: LOGIQBOOK  
SE DECISION MADE: 16-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GENERAL ELECTRIC MEDICAL SYSTEMS  
ATTN: DAVID WAHLIG  
8200 WEST TOWER AVE.  
MILWAUKEE, WI 53223

510(k) NO: K014108  
PHONE NO : 414-362-2090

DEVICE: MAC 5000 ECG ANALYSIS SYSTEM  
SE DECISION MADE: 10-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GERMAINE LABORATORIES, INC.  
ATTN: MARTIN O'CONNOR  
4139 GARDENDALE CENTER  
SUITE 101  
SAN ANTONIO, TX 78229

510(k) NO: K013857  
PHONE NO : 210-692-4192

DEVICE: AIMSTEP PREGNANCY  
SE DECISION MADE: 22-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

GLOBAL HEALTHCARE  
ATTN: ALAM AHMED  
1144 CANTON ST., SUITE 103  
ROSWELL, GA 30075

510(k) NO: K013835  
PHONE NO : 770-522-7520

DEVICE: GLOBAL HEALTHCARE VAGINAL SPECULUM  
SE DECISION MADE: 17-JAN-2002  
510(k) STATEMENT

GOTTLIEB WEINMANN  
ATTN: ECKHARDT ALBERS  
KRONSAALSWEG 40  
HAMBURG,

510(k) NO: K013738  
PHONE NO : 011 494 0547020

DEVICE: WEINMANN SOMNOMASK  
SE DECISION MADE: 22-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 13

GREAT GLOVE (THAILAND) CO. LTD. ATTN: KM LEE 180/3 M. 7 SRISONIHON RD. T. SRISONIHON, A. THALANG, PHUKET,	510(k) NO: K013262 PHONE NO : 603 339 21992	DEVICE: POLYMER COATED POWDER FREE LATEX EXAMINATION GLOVES SE DECISION MADE: 22-JAN-2002  510(k) STATEMENT
GUIDANT CARDIAC AND VASCULAR SURGE ATTN: JACQUELINE J JACKSON 1525 O'BRIEN DR. MENLO PARK, CA 94025	510(k) NO: K003889 PHONE NO : 650-470-6200	DEVICE: ANCURE SHEATH MODEL # 40315, 40320, 40325 SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
GUIDANT CORP. OAT HYDROPHILIC COATING, #1009659, ATTN: JENNIFER PAE RIGGS 26531 YNEZ ROAD TEMECULA, CA 92592-4628	510(k) NO: K013833 1009659J, 1009660, 10096 PHONE NO : 909-914-4581	DEVICE: HI-TOQUE BALANCE MIDDLEWEIGHT UNIVERSAL GUIDE WIRE WITH HYDROC SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
GUIDANT CORP. ATTN: SABA MODJARRAD 3200 LAKESIDE DR. SANTA CLARA, CA 95054	510(k) NO: K014007 PHONE NO : 408-845-1067	DEVICE: DYNALINK .018 BILIARY SELF-EXPANDING STENT SYSTEM SE DECISION MADE: 07-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
GUIDANT CORP. TEM ATTN: SABA MODJARRAD 3200 LAKESIDE DR. SANTA CLARA, CA 95054	510(k) NO: K014184 PHONE NO : 408-845-1067	DEVICE: MODIFICATION TO DYNALINK .035 BILIARY SELF-EXPANDING STENT SYS SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
GUIDANT CORP. VH-1114 ATTN: ANNE SCHLAGENHAFT 3200 LAKESIDE DRIVE SANTA CLARA, CA 95054	510(k) NO: K014250 PHONE NO : 408-845-1842	DEVICE: 7MM EXTENDED LENGTH ENDOSCOPE, DISSECTION TIPS, MODELS VH-1111, SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
GYNECARE, A DIV. OF ETHICON, INC. SURGICAL MESH FOR PELVIC FLOOR REPAIR ATTN: GREGORY R JONES P.O. BOX 151 SOMERVILLE, NJ 08876-0151	510(k) NO: K013718 PHONE NO : 908-218-2481	DEVICE: GYNEMESH PROLENE SOFT (POLYPROPYLENE) NONABSORBABLE SYNTHETIC SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
H&C MEDICAL DEVICES SPA ATTN: ATTILIO CASTELLI VIA PISA 250 SESTO SAN GIOVANNI,	510(k) NO: K012012 PHONE NO : 390 222 476861	DEVICE: ECG HOME SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
HAEMONETICS CORP. ATTN: JOHN SOKOLOWSKI 400 WOOD RD. P.O. BOX 9114 BRAINTREE, MA 02184	510(k) NO: K014083 PHONE NO : 781-356-9488	DEVICE: HAEMONETICS CELL SAVER 5 AUTOLOGOUS BLOOD RECOVERY SYSTEM SE DECISION MADE: 08-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 14

HEALTH & LIFE CO., LTD. ATTN: SUSAN CHEN 6F,NO.407, CHUNG SHAN RD. SEC.02, CHUNG HO CITY TAIPEI HSIEN,	510(k) NO: K014122 PHONE NO : 886 232 349600	DEVICE: HL168E SE DECISION MADE: 16-JAN-2002  510(k) STATEMENT
HEALTHTECH, INC. ATTN: NOEL L JOHNSON 325 LOS GATOS-SARATOGA ROAD LOS GATOS, CA 95070	510(k) NO: K010577 PHONE NO : 408-395-8210	DEVICE: BODYGEM, MODEL HB211 SE DECISION MADE: 10-JAN-2002 510(k) STATEMENT
HELENA LABORATORIES 5752 ATTN: PATRICIA FRANKS 1530 LINDBERGH DR. P.O. BOX 752 BEAUMONT, TX 77704	510(k) NO: K013078 PHONE NO : 409-842-3714	DEVICE: ACTALYKE MINI ACTIVATED CLOTTING TIME TEST SYSTEM, MODEL 5750/ SE DECISION MADE: 10-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
HILL-ROM MANUFACTURING, , INC. MENT SYSTEM ATTN: CINDY L CROSBY 11000 REGENCY PKWY WEST TOWER, SUITE 205 CARY, NC 27511	510(k) NO: K014094 PHONE NO : 919-468-2300	DEVICE: MODIFICATION TO THE WATCHCHILD OBSTETRICAL PATIENT DATA MANAGE SE DECISION MADE: 11-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
HOLLISTER, INC. ATTN: JOSEPH S TOKARZ 2000 HOLLISTER DR. LIBERTYVILLE, IL 60048	510(k) NO: K013345 PHONE NO : 847-680-2849	DEVICE: INCARE INTERMITTENT CATHETER SE DECISION MADE: 07-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOLLISTER, INC. TER, PLUS KIT ATTN: JOSEPH TOKARZ 2000 HOLLISTER DR. LIBERTYVILLE, IL 60048	510(k) NO: K013483 PHONE NO : 847-680-2849	DEVICE: INCARE ADVANCE; INTERMITTENT CATHETER, PLUS INTERMITTENT CATHE SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: KAREN ARIEMMA 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K014220 PHONE NO : 201-760-8187	DEVICE: T2 FEMORAL NAIL SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
HOWMEDICA OSTEONICS CORP. ATTN: JENNIFER A DAUDELIN 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K014226 PHONE NO : 201-831-5379	DEVICE: UNITRAX MODULAR UNIPOLAR SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 15

HOWMEDICA OSTEONICS CORP. ATTN: KAREN ARIEMMA 59 ROUTE 17 ALLENDALE, NJ 07401-1677	510(k) NO: K014229 PHONE NO : 201-760-8187	DEVICE: MODIFICATION TO OPUS SPINAL SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
HUTCHINSON TECHNOLOGY, INC. ATTN: JOSEPH ORTNER 40 WEST HIGHLAND PARK HUTCHINSON, MN 55350	510(k) NO: K012759 PHONE NO : 320-587-1926	DEVICE: INSPECTRA TISSUE SPECTROMETER SYSTEM (INSPECTRA), MODEL 325 SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
HYDROFERA, LLC. ATTN: HEATHER H BOND 322 MAIN ST., SUITE 1101 WILLIMANTIC, CT 06226	510(k) NO: K013462 PHONE NO : 860-456-0677	DEVICE: HYDROFERA BACTERIOSTATIC WOUND DRESSING SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ICN PHOTONICS LTD. ATTN: MIKE KIERMAN UNITS 1&2 HEOL RHOSYN, DAFEN PARK LLANELLI,	510(k) NO: K013461 PHONE NO : 441 554 755444	DEVICE: NLITE SYSTEM,MODEL A00-1025 SE DECISION MADE: 17-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
ICN PHOTONICS LTD. ATTN: IAN MORTIMER UNITS 1&2 HEOL RHOSYN, DAFEN PARK LLANELLI,	510(k) NO: K014130 PHONE NO : 441 554 755444	DEVICE: NLITE SYSTEM SE DECISION MADE: 08-JAN-2002  510(k) STATEMENT
IMDSOFT, LTD. ATTN: T. WHIT ATHEY 12300 TWINEROOK PARKWAY, SUITE 625 ROCKVILLE, MD 20852	510(k) NO: K012349 PHONE NO : 301-770-9590	DEVICE: METAVISION CLINICAL INFORMATION SYSTEM SE DECISION MADE: 29-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
IMPLEX CORP. ATTN: JOHN SCHALAGO 80 COMMERCE DR. ALLENDALE, NJ 07401-1600	510(k) NO: K010378 PHONE NO : 201-818-1800	DEVICE: HEDROCEL VERTEBRAL BODY REPLACEMENT, MODEL XX-YYY-ZZZZ SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
INTERNATIONAL REMOTE IMAGING SYSTEMS ATTN: CYNTHIA J.M NOLITE 49 PLAIN STREET NORTH ATTLEBORO, MA 02760	510(k) NO: K013783 PHONE NO : 508-643-0434	DEVICE: AUTION MAX AX-4280 URINALYSIS SYSTEM SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
INTERPORE CROSS INTL. SPINAL SYSTEM, MODEL 8130, 8131 ATTN: LYNN M RODARTI 181 TECHNOLOGY DR. IRVINE, CA 92618-2402	510(k) NO: K014145 PHONE NO : 949-453-3200	DEVICE: MODIFICATION TO TELESCOPIC PLATE SPACER THORACOLUMBAR (TPS-TL) SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA



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

05-FEB-2002  
Page 16

INTUITIVE SURGICAL, INC. ATTN: MICHAEL YRAMATEGUI 1340 WEST MIDDLEFIELD RD. MOUNTAIN VIEW, CA 94043	510(k) NO: K013416 PHONE NO : 650-237-7048	DEVICE: INTUITIVE SURGICAL ENDOWRIST ENDOSCOPIC INSTRUMENT FAMILY SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
IRVINE SCIENTIFIC SALES CO., INC. ATTN: WENDELL LEE 2511 DAIMLER ST. SANTA ANA, CA 92705	510(k) NO: K013518 PHONE NO : 800-437-5706	DEVICE: EMBRYO FREEZE MEDIUM, EMBRYO THAW MEDIUM SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
IS2 RESEARCH, INC. ATTN: VICTOR WOODBURN 20 GURDWARA RD., BAYS 3-6 NEPEAN, ONTARIO,	510(k) NO: K013667 PHONE NO : 613 228 8755	DEVICE: BCC GAMMA CAMERA SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ITC, INC. ATTN: JOHN CLAY 8 OLSEN AVENUE EDISON, NJ 08820	510(k) NO: K014008 PHONE NO : 800-272-1252	DEVICE: HEMOCHRON JR. CITRATE APTT CUVETTE SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
IVOCLAR VIVADENT, INC. ATTN: DONNA M HARNETT 175 PINEVIEW DR. AMHERST, NY 14228	510(k) NO: K013584 PHONE NO : 716-691-2260	DEVICE: EXCITE SELF ETCH SE DECISION MADE: 28-JAN-2002 510(k) STATEMENT
IVOCLAR VIVADENT, INC. ATTN: DONNA M HARNETT 175 PINEVIEW DR. AMHERST, NY 14228	510(k) NO: K014082 PHONE NO : 716-691-0010	DEVICE: D.SIGN 53, MODEL NA1012204 SE DECISION MADE: 30-JAN-2002 510(k) STATEMENT
JAS DIAGNOSTIC, INC. ATTN: DAVID JOHNSTON 7220 NW 58TH ST. MIAMI, FL 33166	510(k) NO: K013912 PHONE NO : 305-418-2320	DEVICE: CREATINE KINASE (CK-NAC) SE DECISION MADE: 18-JAN-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: K013838 PHONE NO : 310-410-2769	DEVICE: KSEA CLEARVISION LENS IRRIGATION SYSTEM SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
KAVO AMERICA ATTN: JENNIFER POTTALA 340 EAST MAIN ST. LAKE ZURICH, IL 60047	510(k) NO: K013500 PHONE NO : 800-323-8029	DEVICE: KAVO POLYLUX II SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
KMI DIAGNOSTICS, INC. ATTN: MARK A KOWAL 8201 CENTRAL AVE. NE., STE. P MINNEAPOLIS, MN 55432	510(k) NO: K010790 PHONE NO : 763-780-2955	DEVICE: CORTISOL LIA SE DECISION MADE: 29-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 17

KONICA CORP. ATTN: SHINICHI YAMANAKA 319 AKENO, OBATA-CHO WATARAI-GUN MIE-KEN,	510(k) NO: K013052 PHONE NO : 011 815 96373609	DEVICE: KONICA LASER IMAGER, DRYPRO MODEL 751/752 SE DECISION MADE: 16-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
LATEXX MANUFACTURING SDN.BHD. TH BARRIER-PRO BUTADIENE CO-POLMER ATTN: TEH CHOH SHEE PT. 5054, KAMUNTING INDUSTRIAL ESTATE TAIPING, PERAK,	510(k) NO: K013303 PHONE NO : 605 891 5555	DEVICE: CLEANTEX POWDERFREE SYNTHETIC LATEX EXAMINATION GLOVE MADE WI SE DECISION MADE: 23-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
LIFEGUARD MEDICAL PRODUCTS, INC. ATTN: CRAIG JOHNSON 120 ELM DRIVE PLAINFIELD, IN 46168	510(k) NO: K013421 PHONE NO : 317-837-1111	DEVICE: LIFEGUARD NASAL CPAP MASK AND ACCESSORIES SE DECISION MADE: 08-JAN-2002 510(k) STATEMENT
LIMERICK, INC. ATTN: PATRICIA KELLY 903 NORTH SAN FERNANDO BLVD. SUITE 5 BURBANK, CA 91504	510(k) NO: K012275 PHONE NO : 818-566-3060	DEVICE: P.J.S COMFORT PORTABLE ELECTRIC BREAST PUMP SE DECISION MADE: 07-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
LOBOS LABORATORIES, INC. ATTN: DANIEL J MANELLI 2000 M STREET NW # 700 WASHINGTON, DC 20036-3307	510(k) NO: K014162 PHONE NO : 202-261-1000	DEVICE: MODIFICATION TO OPTIMUM CLEANING, DISINFECTING AND SE DECISION MADE: 15-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
LUMEND, INC. ATTN: MICHAEL A DANIEL 400 CHESAPEAKE DR. REDWOOD CITY, CA 94063	510(k) NO: K011562 PHONE NO : 415-407-0223	DEVICE: LUMEND PERCUTANEOUS CATHETER SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MAXTER GLOVE MANUFACTURING SDN BHD PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS) ATTN: STANLEY THAI 6TH MILES OFF JALAN MERU KLANG SELANGOR,	510(k) NO: K013498 PHONE NO : 603 615 62191	DEVICE: CHLORINATED POWDER FREE LATEX MEDICAL EXAMINATION GLOVES WITH SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
MAXTER GLOVE MANUFACTURING SDN BHD TH PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS) ATTN: STANLEY THAI 6TH MILES OFF JALAN MERU KLANG SELANGOR,	510(k) NO: K013554 PHONE NO : 603 615 62191	DEVICE: POLYMER COATED POWDER FREE LATEX MEDICAL EXAMINATION GLOVES WI SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 18

MEDAMICUS, INC. ATTN: DENNIS S MADISON 15301 HWY. 55 WEST MINNEAPOLIS, MN 55447	510(k) NO: K013120 PHONE NO : 763-559-2613	DEVICE: PERCUTANEOUS INTRODUCER SET, MODEL 042294 SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDI-GLOBE CORP. ATTN: SCOTT KARLER 6202 SOUTH MAPLE AVE., SUITE 131 TEMPE, AZ 85283	510(k) NO: K010549 PHONE NO : 480-897-2772	DEVICE: BILIARY AND PANCREATIC ENDOPROSTHESES (STENTS) SE DECISION MADE: 18-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL BIO CARE SWEDEN AB IONS AND THE REMOVAL OF TATTOOS ATTN: CONNIE W HOY 908 STETSON STREET WOODLAND, CA 95776	510(k) NO: K013365 PHONE NO : 530-666-7616	DEVICE: PROLITE PULSED LIGHT SYSTEM FOR THE TREATMENT OF PIGMENTED LES  SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL BIO CARE SWEDEN AB ATTN: CONNIE W HOY 908 STETSON STREET WOODLAND, CA 95776	510(k) NO: K013366 PHONE NO : 530-666-7616	DEVICE: PROLITE PULSED LIGHT SYSTEM FOR THE REMOVAL OF UNWANTED HAIR SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL DATA ELECTRONICS, INC. MODELS 20400, 20401, 20403, 20411, 20412, 20413, 20414 ATTN: GREGORY ALKIRE 12723 WENIWORKH ST. ARLETA, CA 91331	510(k) NO: K014294 PHONE NO : 818-768-6411	DEVICE: MODIFICATION TO ESCORT II+ 400 SERIES 9(ESCORT PRISM) MONITOR,  SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL INTELLIGENCE MEDIZINTECHNI ATTN: CHRISTIAN MULLER FEYERABENDSTRASSE 13-15 SCHWABMUNCHEN,	510(k) NO: K013391 PHONE NO : 490 823 296920	DEVICE: BODYFIX SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDICAL RESEARCH LABORATORIES, INC ATTN: JOEL ORLINSKY 1000 ASBURY DR. NO.17 BUFFALO GROVE, IL 60089	510(k) NO: K012766 PHONE NO : 847-520-0300	DEVICE: PORTABLE INTENSIVE CARE UNIT SE DECISION MADE: 23-JAN-2002 510(k) STATEMENT
MEDITRON AS ATTN: CHARLES H KYPER 103 NOLEN LANE CHAPEL HILL, NC 27516	510(k) NO: K013725 PHONE NO : 919-960-0049	DEVICE: MEDITRON II THESTERIHOSCOPE SYSTEM SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDSTONE INTL., INC. ATTN: RON BERGESON 100 COLUMBIA, SUITE 100 ALISO VIEJO, CA 92656-4114	510(k) NO: K013620 PHONE NO : 949-448-7700	DEVICE: MEDSTONE, UROPRO 2000, TOMOGRAPHIC OPTION SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 19

MEDTRONIC AVE, INC. SYSTEM ("BRIDGE SE") ATTN: KEVIN DRISCO 2170-A NORTHPOINT PKWY SANTA ROSA, CA 95407	510(k) NO: K014205 PHONE NO : 707-541-3193	DEVICE: MODIFICATION TO BRIDGE SELF-EXPANDING BILIARY STENT DELIVERY S SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC PERCUSURGE, INC. N SYSTEM ATTN: MATT MOON 540 OAKMEAD PKWY SUNNYVALE, CA 94085	510(k) NO: K014223 PHONE NO : 408-530-2370	DEVICE: MODIFICATION TO GUARDWIRE PLUS TEMPORARY OCCLUSION & ASPIRATIC SE DECISION MADE: 25-JAN-2002 510(k) STATEMENT
MEDTRONIC SOFAMOR DANEK, INC. ATTN: RICHARD W TREHARNE 1800 PYRAMID PL. MEMPHIS, TN 38132	510(k) NO: K013665 PHONE NO : 901-396-3133	DEVICE: PYRAMID ANTERIOR PLATE FIXATION SYSTEM SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC SOFAMOR DANEK, INC. ATTN: RICHARD TREHARNE 1800 PYRAMID PL. MEMPHIS, TN 38132	510(k) NO: K014267 PHONE NO : 901-396-3133	DEVICE: BUTTERFLY PLATE FIXATION SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC SURGICAL NAVIGATION TECH510(k) NO: K012937 ATTN: VICTORIA G RENDON 826 COAL CREEK CIR. LOUISVILLE, CO 80027	PHONE NO : 720-890-3200	DEVICE: KNEE MODULE FOR THE STEALTHSTATION SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC KOMED, INC. ATTN: MARTIN D SARGENT 6743 SOUTHPOINT DR. NORTH JACKSONVILLE, FL 32216	510(k) NO: K014165 PHONE NO : 904-279-7586	DEVICE: STIMULUS - DISSECTION INSTRUMENTS SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MEDTRONIC, INC. URGICAL ABLATION GENERATOR, MODEL ATTN: SCOTT CANDY 7601 NORTHLAND DRIVE MINNEAPOLIS, MN 55428	510(k) NO: K013392 60880 PHONE NO : 763-391-9941	DEVICE: CARADIOBLATE SURGICAL ABLATION PEN, MODEL 60811C; CARADIOBLATE S SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MERETEK DIAGNOSTICS, INC. ATTN: DENISE E SPELLMAN 618 GRASSMERE PARK DR., #20 NASHVILLE, TN 37211	510(k) NO: K014225 PHONE NO : 800-945-8252	DEVICE: BREATHTEK - UBIT UBT FOR H. PYLORI SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
METALOR TECHNOLOGIES USA ATTN: BRUCE BARTON 255 JOHN L. DIETSCH BLVD. NORTH ATTLEBOROUGH, MA 02761	510(k) NO: K013506 PHONE NO : 800-554-5504	DEVICE: YELLOW SPECIAL SE DECISION MADE: 03-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 20

METALOR TECHNOLOGIES USA ATTN: BRUCE A BARTON 255 JOHN L. DIETSCH BLVD. NORTH ATTLEBOROUGH, MA 02761	510(k) NO: K013769 PHONE NO : 800-554-5504	DEVICE: V-GNATHOS SUPRA SE DECISION MADE: 22-JAN-2002 510(k) STATEMENT
METRACOR TECHNOLOGIES, INC. ATTN: GEORGE F MCHUGH 11425 SORRENTO VALLEY ROAD SAN DIEGO, CA 92121	510(k) NO: K011238 PHONE NO : 858-793-3300	DEVICE: RODA (REAL TIME OXYGEN DYNAMICS ANALYSIS) MONITORING SYSTEM SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MHT OPTIC RESEARCH AG ATTN: MARKUS ANGST MANDACHSTR. 50 NIEDERHASLI,	510(k) NO: K012744 PHONE NO : 011 41 18529000	DEVICE: INTRAORAL LENS OPTION TO SPECTROSHADE SE DECISION MADE: 23-JAN-2002 510(k) STATEMENT
MICROLIFE CORP. -3BT0-1, WITH OPTIONAL THERMAL PRINTER, MODEL PR 1KA1 ATTN: SUSAN D GOLDSTEIN-FALK 55 NORTHERN BLVD. SUITE 200 GREAT NECK, NY 11021	510(k) NO: K013485 PHONE NO : 203-431-1511	DEVICE: MICROLIFE UPPER ARM AUTOMATIC BLOOD PRESSURE MONITOR, MODEL BP SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MICROLINE, INC. ABLE TITANIUM CLIPS, MODEL M/L-10 ATTN: JACQUELINE E MASSE 70 WALNUT STREET WELLESLEY, MA 02481	510(k) NO: K013695 PHONE NO : 781-239-8108	DEVICE: MICROLINE INC. REUSABLE LAPAROSCOPIC CLIP APPLIER WITH IMPLANT SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MICROMEDICAL INDUSTRIES, LTD. ATTN: STEPHEN CRESSWELL 11 TECHNOLOGY DR. LABRADOR, QUEENSLAND,	510(k) NO: K013311 PHONE NO : 617 557 39777	DEVICE: MODIFICATION TO: POCKETVIEW ECG SOFTWARE SE DECISION MADE: 03-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MICROPACE PTY. LTD. ATTN: MICHAEL CEJNAR 571 CANTERBURY RD. CAMPSIE, N.S.W.,	510(k) NO: K011826 PHONE NO : 612 978 76166	DEVICE: EPS320 CARDIAC STIMULATOR SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MINNESOTA MINING AND MFG. CO. ATTN: TIERNEY NORSTED 5353 WAYZATA BLVD. SUITE 505 MINNEAPOLIS, MN 55416	510(k) NO: K013228 PHONE NO : 952-946-8080	DEVICE: 3M COMPLY 1248 GAS PLASMA CHEMICAL INDICATOR SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
MISONIX, INC. ATTN: ALBERT F CLANCY 1938 NEW HIGHWAY FARMINGDALE, NY 11735	510(k) NO: K013417 PHONE NO : 516-694-9555	DEVICE: MISONIX IRRIGATION SYSTEM MOEDL BC20P SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 21

MORAX ATTN: BOREK JANIK 13805 WATERLOO ROAD CHELSEA, MI 48118	510(k) NO: K012789 PHONE NO : 734-475-2441	DEVICE: MODIFIED TO LDL/HDL CHOL DIRECT KIT-P.N. 4005, 4103,4123 SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
MORGAN SCIENTIFIC, INC. ATTN: PATRICK MORGAN 151 ESSEX ST. HAVERHILL, MA 01832	510(k) NO: K013752 PHONE NO : 978-521-4440	DEVICE: COMPAS AS (COMPUTERIZED PULMONARY ANALYSIS SYSTEM) SE DECISION MADE: 30-JAN-2002 510(k) STATEMENT
MRI DEVICES CORP. ATTN: THOMAS SCHUBERT 1515 PARAMOUNT DR. SUITE A WAUKESHA, WI 53186	510(k) NO: K013514 PHONE NO : 262-524-1402	DEVICE: PHSL-63 PEDIATRIC HEAD AND SPINE ARRAY COIL SE DECISION MADE: 02-JAN-2002 510(k) STATEMENT
N.S. UNI-GLOVES SDN. BHD. ATTN: ROBERT D VANDER LEEK UG HEALTHCARE (USA) INC 2420 CARSON ST. SUITE 125 TORRANCE, CA 90501	510(k) NO: K013163 PHONE NO : 310-328-7981	DEVICE: UNIGLOVE LANO-E POWDER-FREE LATEX EXAMINATION GLOVES SE DECISION MADE: 22-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
NELCOR PURITAN BENNETT, INC. ATTN: ANTHONY MULLIN 4280 HACIENDA DR. PLEASANTON, CA 94588-2719	510(k) NO: K014121 PHONE NO : 314-654-3049	DEVICE: WARMTOUCH CARDIAC BLANKET,CATALOG # 503-0860 SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
NEOTECH PRODUCTS, INC. ATTN: ARNOLD M HEYMAN 9135-F ALABAMA AVE. CHATSWORTH, CA 91311	510(k) NO: K011564 PHONE NO : 818-700-2600	DEVICE: NEOLEAD SE DECISION MADE: 03-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
NEUROMETRIX, INC. ATTN: SHIELA HEMMON-HEYER 49 PLAIN ST. NORTH ATTLEBORO, MA 02760	510(k) NO: K013459 PHONE NO : 508-643-0434	DEVICE: MODIFICATION OF NC-STAT SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
NEWCARE PRODUCTS LLC. ATTN: T. WHIT ATHEY 12300 TWINBROOK PRKY. SUITE 625 ROCKVILLE, MD 20852	510(k) NO: K013167 PHONE NO : 301-770-9590	DEVICE: MODEL7500 MICROCURRENT TENS DEVICE, MCT-F5, MCT-F50, MCT-F500 SE DECISION MADE: 30-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
NONIN MEDICAL, INC. (NIBP) MONITOR ATTN: RICHARD P BENNETT 2605 FERNEBROOK LANE, NORTH MINNEAPOLIS, MN 55447-4755	510(k) NO: K013319 PHONE NO : 763-577-3166	DEVICE: NONIN MODEL 2120 PULSE OXIMETER AND NONINVASIVE BLOOD PRESSURE SE DECISION MADE: 03-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 22

NOVA BIOMEDICAL CORP. ATTN: PAUL W MACDONALD 200 PROSPECT ST. WALTHAM, MA 02454-9141	510(k) NO: K013729 PHONE NO : 781-894-0800	DEVICE: STAT PROFILE PHOX BASIC ANALYZER SE DECISION MADE: 15-JAN-2002 510(k) STATEMENT
NUMED, INC. ATTN: NICHELLE R LAFLESH 2880 MAIN STREET HOPKINTON, NY 12965	510(k) NO: K013601 PHONE NO : 315-328-4491	DEVICE: NUMED MULLINS PTA CATHETER SE DECISION MADE: 03-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
NUMED, INC. ATTN: NICHELLE R LAFLASH 2880 MAIN ST. HOPKINTON, NY 12965	510(k) NO: K014124 PHONE NO : 315-328-4491	DEVICE: NUMED COEFFICIENT PTV CATHETERS SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
OLYMPUS OPTICAL CO., LTD. ENTS ATTN: LAURA STORMS-TYLER TWO CORPORATE CENTER DRIVE MELVILLE, NY 11747-3157	510(k) NO: K013617 PHONE NO : 631-844-5688	DEVICE: LTF-240 PLEURAVIDEOSCOPE, ITS ACCESSORIES AND ANCILLARY EQUIPM SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ON SITE GAS SYSTEMS, INC. ATTN: C. BARTON GULLONG 100 PRODUCTION COURT NEW BRITAIN, CT 06051	510(k) NO: K014078 PHONE NO : 860-229-2799	DEVICE: ON SITE GAS SYSTEMS PORTABLE OXYGEN GENERATOR SYSTEM SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
OPUS DENT LTD. ATTN: ARAVA HACOEN 117 AHUZAH ST. RA'ANANNA,	510(k) NO: K014100 PHONE NO : 972 977 18130	DEVICE: OPUS SPECTRUM (A MODEL OF OPUS 20), MODEL 2ND SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ORATEC INTERVENTIONS, INC. ATTN: LINDA GUTHRIE 3700 HAVEN CT. MENLO PARK, CA 94025	510(k) NO: K013622 PHONE NO : 650-369-9904	DEVICE: NUCLECTOMY INTRADISCAL CATHETER SE DECISION MADE: 31-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ORGAN RECOVERY SYSTEMS, INC. ATTN: STANLEY J HARRIS 701 EAST BAY STREET SUITE 433 CHARLESTON, SC 29403	510(k) NO: K013575 PHONE NO : 843-722-6756	DEVICE: KPS-I, THE KIDNEY PERFUSION SOLUTION SE DECISION MADE: 25-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
ORTHO-CLINICAL DIAGNOSTICS , FOLATE REAGENT PACK 3, CALIBRATORS ATTN: MARLENE A SHULMAN 100 INDIGO CREEK DR. ROCHESTER, NY 14626-5101	510(k) NO: K013899 PHONE NO : 716-453-4041	DEVICE: VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12, REAGENT PACK 1/2 SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 23

OSTEOBIOLOGICS, INC. ATTN: MARK Q NIEDERAUER UNIVERSITY BUSINESS PARK 12500 NETWORK, SUITE 112 SAN ANTONIO, TX 78249-3308	510(k) NO: K013429 PHONE NO : 210-690-2131	DEVICE: ACTAEON PROBE SE DECISION MADE: 11-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
OSTEOMED CORP. ATTN: DAWN T HOLDEMAN 3750 REALTY RD. ADDISON, TX 75001-4311	510(k) NO: K012486 PHONE NO : 972-241-3401	DEVICE: OSTEOMED BIORESORBABLE FIXATION SYSTEM SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PADPRO LLC. ATTN: DANIEL KAMM P.O.BOX 7007 DEERFIELD, IL 60015	510(k) NO: K014209 PHONE NO : 847-374-1727	DEVICE: PADPRO MODEL 2001, 2001-S, 2001-C, 2001-EPS SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PAIN CONCEPTS, INC. ATTN: RUSSELL PELUEGER 8001 IRVINE CENTER DRIVE 4TH FLOOR IRVINE, CA 92618	510(k) NO: K013513 PHONE NO : 949-754-3035	DEVICE: DEKOMPRESSOR PERCUTANEOUS LUMBAR DISCECTOMY PROBE SE DECISION MADE: 17-JAN-2002  510(k) STATEMENT
PERCLOSE, INC. ATTN: SEVRINA CIUCCI 400 SAGINAW REDWOOD CITY, CA 94063	510(k) NO: K014117 PHONE NO : 650-474-3164	DEVICE: MODIFICATION TO OUTBACK CATHETER SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PERCLOSE, INC. ATTN: SEVRINA CIUCCI 400 SAGINAW REDWOOD CITY, CA 94063	510(k) NO: K014118 PHONE NO : 650-474-3164	DEVICE: MODIFICATION TO SUPERCROSS CATHETER SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PFM PRODUKTE FUR DIE MEDIZIN AG ATTN: SALVADORE F PALOMARES 15 CHEROKEE STREET TRABUCO CANYON, CA 92679	510(k) NO: K011783 PHONE NO : 949-463-6146	DEVICE: MULTI-SNARE SET SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS A, M3840A, M3841A ATTN: TAMARA YOUNT 2401 FOURTH AVE., SUITE 500 SEATTLE, WA 98121	510(k) NO: K013425 PHONE NO : 206-664-5141	DEVICE: HEARTSTREAM/HEARTSTART FR2 AED ECG CABLE, MODELS M3860A, M3861  SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS 1, M3840A, M3841A ATTN: TAMARA YOUNT 2401 FOURTH AVE., SUITE 500 SEATTLE, WA 98121	510(k) NO: K014157 PHONE NO : 206-664-5000	DEVICE: HEARTSTREAMFR2 AED WITH M3848A AND M3849A, MODELS M3860A, M386  SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA



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

05-FEB-2002  
Page 24

PHILIPS MEDICAL SYSTEMS ATTN: STEVE SINGLAR 3000 MINUTEMAN RD. ANDOVER, MA 01810-1099	510(k) NO: K014191 PHONE NO : 978-659-2101	DEVICE: M2540 DIAGNOSTIC ULTRASOUND SYSTEM, MODEL M2540 SE DECISION MADE: 07-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS NORTH AMER ATTN: LYNN HARMER 22100 BOTHELL EVERETT HWY P.O. BOX 3003 BOTHELL, WA 98041-3003	510(k) NO: K013894 PHONE NO : 425-487-7312	DEVICE: TRANSMIT/RECEIVE QUADRATURE BODY COIL 3.0T SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS(CLEVELAND) ATTN: DUANE C PRASCHAN 595 MINER RD. HIGHLAND HEIGHTS, OH 44143	510(k) NO: K013858 PHONE NO : 440-483-5743	DEVICE: INFINION 0.6T MR IMAGING SYSTEM SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILAABLE FROM FDA
PHILIPS MEDICAL SYSTEMS, INC. V24/V26 PATIENT MONITOR ATTN: DAVE OSBORN 3000 MINUTEMAN RD. ANDOVER, MA 01810-1099	510(k) NO: K014159 PHONE NO : 978-659-3173	DEVICE: PHILLIPS M1175A/76A/77A COMPONENT MONITORING SYSTEM; PHILLIPS SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PHILIPS MEDICAL SYSTEMS, INC. ATTN: MIKE HUDON 3000 MINUTEMAN RD. MS 0491 ANDOVER, MA 01810-1099	510(k) NO: K014181 PHONE NO : 978-659-3173	DEVICE: M2376A DEVICELINK SYSTEM, MODEL M2376A SE DECISION MADE: 15-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PLANMED OY ATTN: BOB PIENKOWSKI 1250 GREENBRIAR, SUITE A ADDISON, IL 60101	510(k) NO: K013656 PHONE NO : 630-953-2368	DEVICE: PLANMED SOPHIE & PLANMED SOPHIE CLASSIC SE DECISION MADE: 16-JAN-2002 510(k) STATEMENT
PROGES S.A. IP, SILICONE FEMALE FOLEY CATHETER, STRAIGHT CYLINDRICAL, ATTN: BERNARD ISMAEL USINE DU PONTET BP 89 SARLAT,	510(k) NO: K013174 PHONE NO : 335 533 13131	DEVICE: PROGES FOLYSIL SILICONE FOLEY CATHETER, STRAIGHT CYLINDRICAL T SE DECISION MADE: 04-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
PRIMUS CORP. ATTN: JIM NOFFSINGER KANSAS CITY, MO 64114	510(k) NO: K014084 PHONE NO : 816-523-7491	DEVICE: NYCOCARD CRP CONTROL 510(k) STATEMENT: 07-JAN-2002
PSYCHEMEDICS CORP. ATTN: WILLIAM R TISTLE 5832 UPLANDER WAY CULVER CITY, CA 90230	510(k) NO: K011185 PHONE NO : 617-868-7455	DEVICE: PSYCHEMEDICS RIA METHAMPHETAMINE AND MDMA ASSAY SE DECISION MADE: 24-JAN-2002 510(k) SUMMARY AVAILAABLE FROM FDA

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

05-FEB-2002  
Page 25

PULSE METRIC, INC. ATTN: ROBERT DUFFY 11777 SORRENTO VALLEY ROAD SAN DIEGO, CA 92121	510(k) NO: K013478 PHONE NO : 858-480-1171	DEVICE: DYNAPULSE 5200A PATHWAY BLOOD PRESSURE MONITORING SYSTEM SE DECISION MADE: 10-JAN-2002 510(k) STATEMENT
QUANTECH LTD. AQ TOTAL HCG TEST CARTRIDGE ATTN: ROBIN J HELLEN 9418 LASAINE AVE NORTHRIDGE, CA 91325	510(k) NO: K012943 PHONE NO : 818-709-5646	DEVICE: THE QUANTECH FASTRAQ AUTOMATED ANALYZER, AND THE QUANTECH PREP SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
R & D SYSTEMS, INC. ATTN: RALPH E HOGAN CAMP 614 MCKINLEY PL., N.E. MINNEAPOLIS, MN 55413	510(k) NO: K013898 PHONE NO : 612-379-2956	DEVICE: R&D RET-LINE KIT SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
RANDOX LABORATORIES, LTD. ATTN: PAULINE ARMSTRONG 55 DIAMOND RD. CRUMLIN, COUNTY ANTRIM,	510(k) NO: K011648 PHONE NO : 441 849 422413	DEVICE: RANDOX CARBAMAZEPINE SE DECISION MADE: 15-JAN-2002 510(k) STATEMENT
RANDOX LABORATORIES, LTD. ATTN: PAULINE ARMSTRONG 55 DIAMOND RD. CRUMLIN, COUNTY ANTRIM,	510(k) NO: K011649 PHONE NO : 441 849 422413	DEVICE: RANDOX VALPROIC ACID SE DECISION MADE: 15-JAN-2002 510(k) STATEMENT
RANDOX LABORATORIES, LTD. ATTN: P ARMSTRONG 55 DIAMOND RD. CRUMLIN, COUNTY ANTRIM,	510(k) NO: K011771 PHONE NO : 440 289 4422413	DEVICE: RANDOX THEOPHYLLINE SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
RANDOX LABORATORIES, LTD. ATTN: PAULINE ARMSTRONG 55 DIAMOND RD. CRUMLIN, COUNTY ANTRIM,	510(k) NO: K012112 PHONE NO : 440 289 4422413	DEVICE: RANDOX DIGITOXIN SE DECISION MADE: 11-JAN-2002 510(k) STATEMENT
RAVEN BIOLOGICAL LABORATORIES, INC ATTN: WENDY ROYALTY-HANN 8607 PARK DR. OMAHA, NE 68127	510(k) NO: K020026 PHONE NO : 402-593-0781	DEVICE: RAVEN BACTERIAL SPORE STRIPS SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
RESPIRONICS GEORGIA, INC. ATTN: BETSY CORTELLONI 175 CHASTAIN MEADOWS COURT KENNESAW, GA 30144-3724	510(k) NO: K011597 PHONE NO : 770-429-1212	DEVICE: SMARIMONITOR 2, MODEL 4000 SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 26

RESPIRONICS, INC. ATTN: DAVID J VANELLA 1001 MURRY RIDGE LANE MURRYSVILLE, PA 15668	510(k) NO: K012554 PHONE NO : 724-733-5866	DEVICE: REMSTAR AUTO CPAP SYSTEM SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
RHODIA INC. ATTN: ALAIN MORIN 320 W. STANLEY AVE VENTURA, CA 93001	510(k) NO: K013859 PHONE NO : 805-653-5638	DEVICE: RHODIA BITE REGISTRATION MATERIAL SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
RIBBOND, INC. ATTN: SHOSHANA RUDO DRIVER 1402 3RD AVE., SUITE 1030 SEATTLE, WA 98101-2118	510(k) NO: K013881 PHONE NO : 206-340-8870	DEVICE: RIBBOND - TRIAXIAL SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
RICH-MAR CORP. ATTN: DAVID RICHARDS 15499 EAST 590TH RD. P.O. BOX 879 INOLA, OK 74036	510(k) NO: K013770 PHONE NO : 918-543-2222	DEVICE: MODIFICATION TO: WINNER ST-2 STIMULATOR SE DECISION MADE: 18-JAN-2002  510(k) STATEMENT
RICH-MAR CORP. TIC ULTRASOUND AND COMBINATION DEVICE ATTN: DAVID RICHARDS 15499 EAST 590TH RD. P.O. BOX 879 INOLA, OK 74036	510(k) NO: K013771 PHONE NO : 918-543-2222	DEVICE: MODIFICATION TO: WINNER CM-2 MUSCLE STIMULATOR, TENS, THERAPEU SE DECISION MADE: 18-JAN-2002  510(k) STATEMENT
RICHARD WOLF MEDICAL INSTRUMENTS , 1 CCD CAMERA HEAD PAL, LIGHT PROJECTOR, MODEL 5551.107 ATTN: ROBERT L CASARSA 353 CORPORATE WOODS PKWY. VERNON HILLS, IL 60061	510(k) NO: K010033 PHONE NO : 847-913-1113	DEVICE: LIGHT PROJECTOR WITH ENDOSCOPIC CAMERA, 1 CCD CAMERA HEAD NTSC SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ROC CHINESE-EUROPEAN INDUSTRIAL RE ATTN: JEN KE-MIN NO.58, FU-CHIUN STREET, HSIN-CHU CITY,	510(k) NO: K011846 PHONE NO : 886 352 08829	DEVICE: BIOTECH POWERED WHEELCHAIR, C650FW SE DECISION MADE: 18-JAN-2002 510(k) STATEMENT
ROCHE DIAGNOSTICS CORP. ATTN: MIKE FLIS 9115 HAGUE RD. INDIANAPOLIS, IN 46250	510(k) NO: K013757 PHONE NO : 800-428-5074	DEVICE: ROCHE ACETAMINOPHEN SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ROSSMAX INTERNATIONAL LTD. NITORS ATTN: MICHAEL YEH 12F., NO.189, KANG CHIEN RD. TAIPEI,	510(k) NO: K013539 PHONE NO : 011 886 226597888	DEVICE: ROSSMAX MEDIPRO, MODELS 100F, 200F, AND 300F BLOOD PRESSURE MC SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT

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

05-FEB-2002

Page 27

ROSSMAX INTERNATIONAL LTD. D PRESSURE MONITORS ATTN: MICHAEL YEH 12F., NO.189, KANG CHIEN RD. TAIPEI,	510(k) NO: K013583 PHONE NO : 011 886 2265978888	DEVICE: ROSSMAX MEDIPRO MODEL 10 AND 60, MEDICARE MODEL 10 AND 60 BLOC SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
SCIENT'X ATTN: JOANNA DROEGE 9800 METRIC BLVD. AUSTIN, TX 78758	510(k) NO: K013439 PHONE NO : 512-832-9500	DEVICE: ANTERIOR CERVICAL PLATE SYSTEM SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SCIENT'X ATTN: JOANNA DROEGE 9800 METRIC BLVD. AUSTIN, TX 78758	510(k) NO: K013447 PHONE NO : 512-832-9500	DEVICE: ISOBAR SPINAL SYSTEM SE DECISION MADE: 15-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SCIENTIFIC PHARMACEUTICALS, INC. ATTN: JAN A ORLOWSKI 3221 PRODUCER WAY POMONA, CA 91768	510(k) NO: K013555 PHONE NO : 909-595-9922	DEVICE: SCI-PHARM POST SECURE SE DECISION MADE: 23-JAN-2002 510(k) STATEMENT
SCOTT E ALLEN CP ATTN: SCOTT E ALLEN 50 SOUTH 900 EAST #1 SALT LAKE CITY, UT 84102	510(k) NO: K012804 PHONE NO : 801-364-3100	DEVICE: PLAGIOCEPHALIC APPLIED PRESSURE ORTHOSIS P.A.P. ORTHOSIS SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SEAL POLYMER INDUSTRIES SDN. BHD. LAIM ON LABELING ATTN: CHUN C FONG LT 72706, JALAN LAHAT, KAWASAN PERINDUSTRIAN BUKIT MERAH LAHAT, IPOH, PERAK,	510(k) NO: K014055 PHONE NO : 605 322 3200	DEVICE: NON-STERILE POWDERED LATEX EXAMINATION GLOVES WITH A PROTEIN C SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SEMPERIT TECHNISCHE PRODUKTE GESELSCHAFT ATTN: JAY MANSOUR 1308 MORNINGSTAR PARK DR APHARETTA, GA 30022	510(k) NO: K013560 PHONE NO : 678-908-8180	DEVICE: SEMPERMED SUPREME, SIZES 5.5, 6, 6.5, 7, 7.5, 8, 8.5, AND 9 SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SENORX, INC. ORLES (POWER CORD, CONNECTOR CORDS AND FOOTSWITCH), VACUUMS ATTN: AMY BOUCLY 11 COLUMBIA, SUITE A ALISO VIEJO, CA 92656	510(k) NO: K013641 PHONE NO : 949-362-4800	DEVICE: SENORX BIOPSY DEVICE, DRIVER, CONTROL MODULE, INCLUDING ACCESS SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SERVOX MEDIZINTECHNIK GMBH ATTN: MARTIN HERBERG 69 SERVATIUSSTRASSE POSTAL CODE 51109 KOLN,	510(k) NO: K013585 PHONE NO : 022 189 9000	DEVICE: MEDIPOINT 2000 MOBILE SE DECISION MADE: 28-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 28

SHARGH PHARMACEUTICAL CO., INC. ATTN: ARMAND HAMEDANI 5840 WEST CENTINELA AVE. BUILDING 2 LOS ANGELES, CA 90045	510(k) NO: K013384 PHONE NO : 310-649-0707	DEVICE: SHARGHP A.V. FISTULA NEEDLE SET SE DECISION MADE: 07-JAN-2002  510(k) STATEMENT
SHEN WEI (USA), INC. D PROTEIN LABELING CLAIMS ATTN: BELLE L CHOU 2845 WHIPPLE RD. UNION CITY, CA 94587	510(k) NO: K013793 PHONE NO : 510-429-8692	DEVICE: POWDER FREE LATEX EXAMINATION GLOVES WITH ALOE VERA @PH 5.5 AN SE DECISION MADE: 22-JAN-2002 510(k) STATEMENT
SHEN WEI (USA), INC. IM, TESTED FOR USE WITH CHEMOTHERAPY DRUGS ATTN: BELLE L CHOU 2845 WHIPPLE RD. UNION CITY, CA 94587	510(k) NO: K013794 PHONE NO : 510-429-8692	DEVICE: POWDER-FREE LATEX EXAMINATION GLOVES WITH ALOE AND PROTEIN CLA SE DECISION MADE: 22-JAN-2002 510(k) STATEMENT
SHEN WEI (USA), INC. IM, TESTED FOR USE WITH CHEMOTHERAPY DRUGS, GREEN COLOR ATTN: BELLE L CHOU 2845 WHIPPLE RD. UNION CITY, CA 94587	510(k) NO: K013795 PHONE NO : 510-429-8692	DEVICE: POWDER-FREE LATEX EXAMINATION GLOVES WITH ALOE AND PROTEIN CLA SE DECISION MADE: 22-JAN-2002 510(k) STATEMENT
SHIRE BIOLOGICS INC. ATTN: ANGELA ROGERS WORLDWIDE REGULATORY AFFAIRS 10182 TELESIS COURT SAN DIEGO, CA 92121	510(k) NO: K013523 PHONE NO : 508-351-1006	DEVICE: CISTEM FLUID TRANSFER DEVICE, MODEL 7S2012 AND 7S2013 SE DECISION MADE: 07-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
SHOPRIDER INTL., INC. ATTN: CHRIS TINSLEY P.O. BOX 187 NEODESHA, KS 66757	510(k) NO: K013927 PHONE NO : 620-325-2629	DEVICE: MINI SHOPPER SE DECISION MADE: 28-JAN-2002 510(k) STATEMENT
SIEMENS ELEMA AB ATTN: DIANE WURZBURGER MEDICAL SOLUTIONS 186 WOOD AVENUE SOUTH ISELIN, NJ 08830-2770	510(k) NO: K010923 PHONE NO : 732-321-4765	DEVICE: KION ANAESTHESIA SYSTEM, MODEL 65 03 879 E392E SE DECISION MADE: 23-JAN-2002  510(k) SUMMARY AVAILABLE FROM FDA
SIEMENS MEDICAL SOLUTIONS USA, INC ATTN: PENELOPE H GRECO 16 ELECTRONICS AVE. DANVERS, MA 01923	510(k) NO: K013515 PHONE NO : 978-907-7500	DEVICE: INFINITY EXPLORER SE DECISION MADE: 10-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 29

SIEMENS MEDICAL SOLUTIONS USA, INC 510(k) NO: K014213  
ATTN: PENELOPE H GRECO PHONE NO : 978-907-7500  
16 ELECTRONICS AVE.  
DANVERS, MA 01923

DEVICE: SIEMENS INFINITY GATEWAY SUITE  
SE DECISION MADE: 17-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

SLE LIMITED 510(k) NO: K011842  
ATTN: FRANK FERGUSON PHONE NO : 858-587-1147  
PO BOX 12038  
LA JOLLA, CA 92039-2038

DEVICE: SABRE COMPAC  
SE DECISION MADE: 08-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

SMITH & NEPHEW, INC. 510(k) NO: K013870  
NEPHEW CONTINUOUS FLOW SHEATH, MODEL 8105224  
ATTN: JANICE HASELTON PHONE NO : 978-749-1000  
160 DASCONE RD.  
ANDOVER, MA 01810

DEVICE: SMITH & NEPHEW OPERATIVE HYSTEROSCOPE, MODEL 7209208; SMITH &  
SE DECISION MADE: 17-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

SORBA MEDICAL SYSTEMS, INC. 510(k) NO: K014299  
ATTN: JILL BARNEY PHONE NO : 262-827-2740  
165 BISHOPS WAY, SUITE 152  
BROOKFIELD, WI 53005

DEVICE: SORBA STEORRA NON-INVASIVE IMPEDANCE CARDIOGRAPH  
SE DECISION MADE: 30-JAN-2002  
510(k) STATEMENT

SPINAL INNOVATIONS, LLC. 510(k) NO: K013196  
ATTN: KENNETH RUSSELL PHONE NO : 901-373-8855  
7850 STAGE HILLS BLVD.  
SUITE 105  
BARILETT, TN 38133

DEVICE: ASCEND SPINAL FIXATION SYSTEM WITH THE SHADOW SPINAL SYSTEM  
SE DECISION MADE: 30-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

SSN MEDICAL PRODUCTS SDN. BHD. 510(k) NO: K013773  
ATTN: ANG TECK LEONG PHONE NO : 6 03 77812829  
NO. 1, JALAN 203, OFF JALAN  
TANDANG  
PETALING JAYA, SELANGOR,

DEVICE: SAFE  
SE DECISION MADE: 24-JAN-2002  
510(k) STATEMENT

ST. JUDE MEDICAL, INC. 510(k) NO: K014037  
ATTN: WILLIAM MCKELVEY PHONE NO : 651-415-7029  
ONE LILLEHEI PLAZA  
ST. PAUL, MN 55117

DEVICE: SJM SEGUIN ANNULOPLASTY RING (SEGUIN RING), MODEL SARP-(SIZE)  
SE DECISION MADE: 04-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

ST. JUDE MEDICAL, INC. 510(k) NO: K014161  
ATTN: WILLIAM MCKELVEY PHONE NO : 651-415-7029  
ONE LILLEHEI PLAZA  
ST. PAUL, MN 55117

DEVICE: SJM TAILOR ANNULOPLASTY RING MODEL TARP- (SIZE)  
SE DECISION MADE: 15-JAN-2002  
510(k) SUMMARY AVAILABLE FROM FDA

STARBENE 510(k) NO: K992099  
ATTN: JUDITH NITZSCHMAMN PHONE NO : 543 513 4240051  
DAVID LUQUE 519  
CORDOBA, PVCA. CORDOBA,

DEVICE: BIO SPA INTELLIGENT  
SE DECISION MADE: 18-JAN-2002  
510(k) STATEMENT

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

05-FEB-2002  
Page 30

STELKAST CO. ATTN: DONALD A STEVENS 800 VINAL ST. #210 PITTSBURGH, PA 15212	510(k) NO: K014049 PHONE NO : 412-322-8280	DEVICE: EPOCA CODR SIEM AND HEAD SE DECISION MADE: 09-JAN-2002 510(k) STATEMENT
STELLATE SYSTEMS ATTN: GEORGE PAPAGIANNIS 345 VICTORIA AVE., SUITE 300 WESTMOUNT, QUEBEC,	510(k) NO: K013450 PHONE NO : 514 486 1306	DEVICE: NOTTA AMBULATORY RECORDER SE DECISION MADE: 14-JAN-2002 510(k) STATEMENT
STERILMED, INC. ATTN: PATRICK FLEISCHACKER 11400 73RD AVE. NORTH MAPLE GROVE, MN 55369	510(k) NO: K012684 PHONE NO : 888-856-4870	DEVICE: REPROCESSED ELECTROSURGICAL ELECTRODE SE DECISION MADE: 18-JAN-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: K014061 PHONE NO : 650-949-0470	DEVICE: SIMPLICITY STARPLUS SOFT INFUSION SET SE DECISION MADE: 17-JAN-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: K014062 PHONE NO : 650-949-0470	DEVICE: SIMPLICITY EASY ACCESS INFUSION SET SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
STRYKER LEIBINGER ATTN: ROBIN L ROWE 4100 EAST MILHAM AVE KALAMAZOO, MI 49001	510(k) NO: K013775 PHONE NO : 877-534-2464	DEVICE: TWINFIX INTERFRAGMENTARY COMPRESSION SCREW SYSTEM SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SULZER DENTAL, INC. ATTN: FOSTER BOOP 1900 ASTON AVE. CARLSBAD, CA 92008-7308	510(k) NO: K013494 PHONE NO : 760-929-4300	DEVICE: 3.75MM AND 5.0MM SPLINE TWIST IMPLANT SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SULZER INTRATHERAPEUTICS, INC. PORT DELIVERY TECHNOLOGY ATTN: MARIA E BRITTLE 651 CAMPUS DR. ST. PAUL, MN 55112-3495	510(k) NO: K014136 PHONE NO : 651-697-9797	DEVICE: MODIFICATION TO PROTEGE SELF-EXPANDING NITINOL STENT WITH STAR SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SUPERGRADE HEALTHCARE PRODUCTS ATTN: JANNA P TUCKER 198 AVENUE DE LA D'EMERALD SPARKS, NV 89434-9550	SDN510(k) NO: K014134 PHONE NO : 775-342-2612	DEVICE: POWDER-FREE LATEX EXAM GLOVES WITH PROTEIN LABELING (<50UG/G) SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 31

SUPERMAX GLOVE MANUFACTURING SDN B510(k) NO: K013589 ALOE VERA ATTN: STANLEY THAI LOT 42, PUTRA INDUSTRIAL PARK BUKIT RAHMAN PUTRA SUNGAI BULOH, SELANGOR,	PHONE NO : 603 615 72328	DEVICE: CHLORINATED POWDER FREE LATEX MEDICAL EXAMINATION GLOVES WITH SE DECISION MADE: 08-JAN-2002 510(k) STATEMENT
SURGICAL SPECIALTIES CORP. UTURE, UNDYED ATTN: ELIZABETH LAZARO 100 DENNIS DRIVE READING, PA 19606-3776	510(k) NO: K014021 PHONE NO : 610-404-1000	DEVICE: SHARPOINT COATED, FAST ABSORBING POLYGLYCOLIC ACID SYNTHETIC S SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SURX, INC. SORIES (SURX LP SYSTEM) ATTN: ALAN CURTIS 6900 KOLL CENTER PKWY., #417 PLEASANTON, CA 94566	510(k) NO: K011190 PHONE NO : 925-417-1400	DEVICE: SURX RADIOFREQUENCY ELECTROSURGICAL GENERATOR SYSTEM AND ACCES SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SWIFT DELIVERY PRODUCTS ATTN: RICHARD G LINDSAY 6824 ELK CANYON RD. OKLAHOMA CITY, OK 73162	510(k) NO: K013460 PHONE NO : 405-721-8227	DEVICE: SWIFT LOW PROFILE CUP (PRO CUP) SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
SYERON DENTAL SPECIALTIES, INC. ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92867	510(k) NO: K013510 PHONE NO : 714-516-7484	DEVICE: POINT 4 MODIFIED SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SYERON DENTAL SPECIALTIES, INC. ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92867	510(k) NO: K013529 PHONE NO : 714-516-7484	DEVICE: POINT 4 TRANSLUCENT MODIFIED SE DECISION MADE: 09-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SYERON DENTAL SPECIALTIES, INC. ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92867	510(k) NO: K013609 PHONE NO : 714-516-7484	DEVICE: NEXUS 2 CLEAR SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SYERON DENTAL SPECIALTIES, INC. ATTN: COLLEEN BOSWELL 1717 WEST COLLINS AVENUE ORANGE, CA 92867	510(k) NO: K013647 PHONE NO : 714-516-7484	DEVICE: REVOLUTION FORMULA 2 SE DECISION MADE: 16-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
SYNTHES (USA) ATTN: THOMAS M MAGUIRE 1690 RUSSELL ROAD POST OFFICE BOX 1766 PAOLI, PA 19301	510(k) NO: K011583 PHONE NO : 610-647-9700	DEVICE: SPIKED WASHER SE DECISION MADE: 30-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA



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

05-FEB-2002  
Page 32

SYNTHES (USA) ATTN: MATTHEW M HULL 1690 RUSSELL RD. PAOLI, PA 19301	510(k) NO: K013415 PHONE NO : 610-647-9700	DEVICE: SYNTHES ANKLE ARTHRODESIS PLATE SE DECISION MADE: 11-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
TERUMO CARDIOVASCULAR SYSTEMS CORP ATTN: GARRY A COURTNEY 125 BLUE BALL ROAD ELKTON, MD 21921	510(k) NO: K013578 PHONE NO : 800-283-7866	DEVICE: PUMP TUBING SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
TETRAD CORP. CERS ATTN: CHARLES F HOTTINGER 357 INVERNESS DR. SOUTH, SUITE A ENGLEWOOD, CO 80112	510(k) NO: K014182 PHONE NO : 408-741-1006	DEVICE: TETRAD MODEL TC-C52-, -C84V-, -C95-, -CLA76-, -L74-ATP TRANSDU SE DECISION MADE: 03-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
THERMAGE, INC. ATTN: PAMELA M BUCKMAN 4058 POINT EDEN WAY HAYWARD, CA 94545-3721	510(k) NO: K013639 PHONE NO : 510-259-7116	DEVICE: THERMAGE THERMACOOL TC SYSTEM SE DECISION MADE: 29-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
TISSUE SCIENCE LABORATORIES, PLC ATTN: HOWARD M HOLSTEIN 555 THIRTEENTH ST. N.W. WASHINGTON, DC 20004-1109	510(k) NO: K013625 PHONE NO : 202-637-5600	DEVICE: PERMACOL SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
TOMO THERAPY INC ATTN: KENNETH D BUROKER 2228 EVERGREEN ROAD MIDDLETON, WI	510(k) NO: K013673 PHONE NO : 608-824-0995	DEVICE: HI-ART SYSTEM SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
TRINITY BIOTECH, PLC ATTN: FIONA CAMPBELL IDA BUSINESS PARK BRAY CO. WICKLOW,	510(k) NO: K014233 PHONE NO : 011 353 12769800	DEVICE: CAPTIAM SYPHILIS-G ASSAY SE DECISION MADE: 24-JAN-2002 510(k) STATEMENT
TUCO INNOVATIONS, INC. ATTN: KEVIN WALL 13 RED FOX LANE LITTLETON, CO 80127	510(k) NO: K012580 PHONE NO : 720-962-5412	DEVICE: ERCHONIA PL2000 SE DECISION MADE: 17-JAN-2002 510(k) STATEMENT
UNITED STATES SURGICAL, A DIVISION ATTN: ROBERT ZOIT 150 GLOVER AVE. NORWALK, CT 06856	510(k) NO: K013671 PHONE NO : 203-845-4515	DEVICE: L-25 ABSORBABLE SURIGCAL SUTURE SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 33

USA INSTRUMENTS, INC. ATTN: RONY THOMAS 1515 DANNER DRIVE AURORA, OH 44202	510(k) NO: K013592 PHONE NO : 330-562-1000	DEVICE: EXTREMITY COIL SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
USA INSTRUMENTS, INC. ATTN: RONY THOMAS 1515 DANNER DRIVE AURORA, OH 44202	510(k) NO: K013594 PHONE NO : 330-562-1000	DEVICE: BODY ARRAY COIL SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
USA INSTRUMENTS, INC. ATTN: RONY THOMAS 1515 DANNER DRIVE AURORA, OH 44202	510(k) NO: K013595 PHONE NO : 330-562-1000	DEVICE: PREMIER III PHASED ARRAY CTL SPINE COIL SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VANGUARD MEDICAL CONCEPTS, INC. ATTN: MIKE SAMMON 5307 GREAT OAK DR. LAKELAND, FL 33815	510(k) NO: K012480 PHONE NO : 863-683-8680	DEVICE: VANGUARD REPROCESSED INFLATION DEVICES SE DECISION MADE: 22-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VASCULAR SOLUTIONS, INC. ATTN: DEBORAH L JENSEN 2495 XENIUM LANE NORTH MINNEAPOLIS, MN 55441	510(k) NO: K012293 PHONE NO : 763-656-4349	DEVICE: VASCULAR SOLUTIONS DUETT FLOWABLE HEMOSTAT SE DECISION MADE: 18-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VASOCOR, INC. ATTN: WALTER M ROSEBROUGH 499 A JESSEN LANE CHARLESTON, NC 29492	510(k) NO: K011625 PHONE NO : 305-592-7260	DEVICE: VASOCOR VASCULAR DIAGNOSTIC CENTER (MODEL 300) SE DECISION MADE: 23-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VENTREX, INC. ATTN: ROBERT GUTHRIE 3007 BUNSEN AVE., UNIT L & K VENTURA, CA 93003	510(k) NO: K013477 PHONE NO : 805-658-2984	DEVICE: TOCO LITE, MODEL TD-01 SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VIDAMED, INC. ATTN: YI CHEN 46107 LANDING PKWY. FREMONT, CA 94538	510(k) NO: K014224 PHONE NO : 510-492-4900	DEVICE: PRECISION PLUS TUNA OFFICE SYSTEM SE DECISION MADE: 23-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VON ZEPPELIN GMBH ATTN: DIETER VON ZEPPELIN GISTLSTRASSE 99 PULLACH,	510(k) NO: K013091 PHONE NO : 498 979 36880	DEVICE: ZMM 2000 ZEPPELIN MILLENNIUM MOTORDRILL SYSTEM SE DECISION MADE: 25-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
VOXAR LIMITED ATTN: CONRAD CMIN BONNINGTON BOND, 2 ANDERSON PL EDINBURGH,	510(k) NO: K020140 PHONE NO : 440 131 4723792	DEVICE: VOXAR'S CALCIUM SCORING PRODUCT SE DECISION MADE: 28-JAN-2002 510(k) STATEMENT

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

05-FEB-2002  
Page 34

VYGON CORP. ATTN: ROBERT SCHIFF 1129 BLOOMFIELD AVE. WEST CALDWELL, NJ 07006	510(k) NO: K003311 PHONE NO : 973-227-1830	DEVICE: NUTRISAFE PUR ENTERAL FEEDING TUBE SE DECISION MADE: 11-JAN-2002 510(k) STATEMENT
W.L. GORE & ASSOCIATES, INC ATTN: TIMOTHY J RYNN 3750 WEST KILLTIE LN. FLAGSTAFF, AZ 86002-0900	510(k) NO: K013648 PHONE NO : 928-864-3714	DEVICE: VIABAHN ENDOPROSTHESIS SE DECISION MADE: 08-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
WALTER LORENZ SURGICAL, INC. ATTN: KIM REED 1520 TRADEPORT DR. JACKSONVILLE, FL 32218	510(k) NO: K014148 PHONE NO : 904-741-4400	DEVICE: SELF-DRILLING RADIOGRAPHIC MARKER SE DECISION MADE: 17-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
WIENER LABORATORIES S.A.I.C. ATTN: VIVIANA CETOLA 2944 RIOBAMBA ROSARIO,	510(k) NO: K013983 PHONE NO : 54 341 4329191	DEVICE: WIENER LAB. ALP 405 SE DECISION MADE: 28-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
WRP ASIA PACIFIC SDN. BHD. TEIN LABELING CLAIM) ATTN: YUE W CHOW LOT 1, JALAN 3, KAWASAN PERUSAHAAN BANDAR BARU SALAK TINGGI, SEPANG SELANGOR,	510(k) NO: K020019 PHONE NO : 011 603 87061486	DEVICE: POWDER FREE POLYMER COATED LATEX SURGICAL GLOVES, STERILE (PRC SE DECISION MADE: 23-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
XLTEK ATTN: SONJA MARKEZ 2568 BRISTOL CIRCLE OAKVILLE,	510(k) NO: K014146 PHONE NO : 905 829 5300	DEVICE: 84 CHANNEL EEG SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
XLTEK ATTN: SONJA MARKEZ 2568 BRISTOL CIRCLE OAKVILLE,	510(k) NO: K014147 PHONE NO : 905 829 5300	DEVICE: 80 CHANNEL EEG SE DECISION MADE: 14-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA
ZIMMER, INC. ATTN: STEPHEN MCKELVEY P.O. BOX 708 WARSAW, IN 46581-0708	510(k) NO: K013385 PHONE NO : 219-372-4944	DEVICE: NEXGEN COMPLETE KNEE SOLUTION ROTATING HINGE KNEE SE DECISION MADE: 09-JAN-2002 510(k) SUMMARY AVAILABLE FROM FDA

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

05-FEB-2002  
Page 35

TOTAL 510(k)s THIS PERIOD	304
TOTAL WITH SUMMARIES	232
TOTAL WITH STATEMENTS	72