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## Medical Devices

### January 2007 510(k) Clearances

SUBMITTER ADDRESS LISTING FOR CDRH SUBSTANTIALLY EQUIVALENT (SE)  
510(K) SUMMARIES OR 510(K) STATEMENTS FOR FINAL  
DECISIONS RENDERED DURING THE PERIOD 01-JAN-2007 THROUGH 31-JAN-2007

DEVICE: A&D MEDICAL UA-789 DIGITAL BLOOD PRESSURE MONITOR  
A & D ENGINEERING, INC. 510(k) NO: [K062027](#)<sup>1</sup>(SPECIAL)  
ATTN: JERRY WANG PHONE NO : 408-518-5113  
1555 MCCANDLESS DR. SE DECISION MADE: 19-JAN-07  
MILPITAS, CA 95035 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ACCIN UNI-KNEE SYSTEM  
ACCIN CORPORATION 510(k) NO: [K063782](#)<sup>2</sup>(SPECIAL)  
ATTN: MICHAEL KBITNITSKY PHONE NO : 973-777-8832  
1033 US HIGHWAY 46 EAST SE DECISION MADE: 19-JAN-07  
SUITE A204 510(k) SUMMARY AVAILABLE FROM FDA  
CLIFTON, NJ 07013

DEVICE: AESCULAP-MEITHEKE PROGAV PROGRAMMABLE VALVE, MODELS FV410T-FV451T  
AESCULAP, INC. 510(k) NO: [K062009](#)<sup>3</sup>(TRADITIONAL)  
ATTN: MATTHEW M HULL PHONE NO : 610-984-9072  
3773 CORPORATE PKWY. SE DECISION MADE: 17-JAN-07  
CENTER VALLEY, PA 18034 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LIBERTY BLOOD GLUCOSE MONITORING SYSTEM, MODEL 8000-0067  
AGAMATRIX 510(k) NO: [K063409](#)<sup>4</sup>(TRADITIONAL)  
ATTN: CONNIE HERTEL PHONE NO : 603-328-6051  
10 MAOR PARKWAY SE DECISION MADE: 12-JAN-07  
SALEM, NH 03079 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: RELIANCE CI PROCESS INDICATOR  
ALBERT BROWNE LTD. 510(k) NO: [K063285](#)<sup>5</sup>(TRADITIONAL)  
ATTN: CYNTHIA J.M. NOLTE PHONE NO : 919-859-4207  
49 PLAIN STREET SE DECISION MADE: 12-JAN-07  
NORTH ATTLEBORO, MA 02760 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: THERMOGARD THERMAL REGULATION SYSTEM  
ALSISIUS CORP. 510(k) NO: [K063829](#)<sup>6</sup>(SPECIAL)  
ATTN: KENNETH A COLLINS PHONE NO : 949-453-0150  
15770 LAGUNA CANYON, SUITE 150 SE DECISION MADE: 22-JAN-07  
IRVINE, CA 92618 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: AERO TRACHEOBRONCHIAL STENT SYSTEM, MODEL 90129-2XX  
ALVEOLUS, INC. 510(k) NO: [K062511](#)<sup>7</sup>(TRADITIONAL)  
ATTN: DONALD CANAL PHONE NO : 704-926-4850  
9013 PERIMETER WOODS DRIVE SE DECISION MADE: 31-JAN-07  
SUITE A 510(k) SUMMARY AVAILABLE FROM FDA  
CHARLOTTE, NC 28216

DEVICE: ALEXIS WOUND RETRACTOR  
APPLIED MEDICAL RESOURCES 510(k) NO: [K062907](#)<sup>8</sup>(TRADITIONAL)  
ATTN: CHERYL BLAKE PHONE NO : 949-713-8000  
22872 AVENIDA EMPRESA SE DECISION MADE: 09-JAN-07  
RANCHO SANTA MARGARITA, CA 92688 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: AR1000 ULTRASONIC WOUND THERAPY SYSTEM

AROBELLA MEDICAL, LLC 510(k) NO: [K062544](#)<sup>9</sup>(TRADITIONAL)  
ATTN: ALLISON SCOTT PHONE NO : 317-569-9500  
11460 N. MERIDIAN STREET SE DECISION MADE: 03-JAN-07  
SUITE 150 510(k) SUMMARY AVAILABLE FROM FDA  
CARMEL, IN 46032

## DEVICE: ARTHREX ANATOEMIC PHALANGEAL PROSTHESIS

ARTHREX, INC. 510(k) NO: [K063058](#)<sup>10</sup>(TRADITIONAL)  
ATTN: NANCY HOFT PHONE NO : 239-643-5553  
1370 CREEKSIDE BLVD. SE DECISION MADE: 03-JAN-07  
NAPLES, FL 34108-1945 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: CAP 7.0MM MTP RESURFACING HEMI-ARTHROPLASTY

ARTHROSURFACE, INC. 510(k) NO: [K063370](#)<sup>11</sup>(TRADITIONAL)  
ATTN: DAWN J WILSON PHONE NO : 508-520-3003  
28 FORGE PARKWAY SE DECISION MADE: 12-JAN-07  
FRANKLIN, MA 02038 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: ASAHI PTCA GUIDE WIRE, FIELDER FC

ASAHI INTECC CO., LTD. 510(k) NO: [K063819](#)<sup>12</sup>(SPECIAL)  
ATTN: YOSHI TERAI PHONE NO : 949-756-8252  
1301 DOVE STREET SE DECISION MADE: 26-JAN-07  
SUITE 350 510(k) SUMMARY AVAILABLE FROM FDA  
NEWPORT BEACH, CA 92660

## DEVICE: REPROCESSED TROCARS

ASCENT HEALTHCARE SOLUTIONS 510(k) NO: [K062497](#)<sup>13</sup>(TRADITIONAL)  
ATTN: ELIZABETH RENKIN PHONE NO : 480-763-5394  
10232 SOUTH 51ST ST. SE DECISION MADE: 31-JAN-07  
PHOENIX, AZ 85044 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: ATRICURE ABLATION SYSTEM

ATRICURE, INC. 510(k) NO: [K063630](#)<sup>14</sup>(TRADITIONAL)  
ATTN: ELSA C ABRUZZO PHONE NO : 513-755-4130  
6033 SCHUMACHER PARK DR. SE DECISION MADE: 26-JAN-07  
WEST CHESTER, OH 45069 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

## DEVICE: DISPOSABLE MONOPOLAR AND BIPOLAR STIMULATOR PROBES

AXON SYSTEMS, INC. 510(k) NO: [K062996](#)<sup>15</sup>(TRADITIONAL)  
ATTN: HOWARD BAILIN PHONE NO : 631-436-5112  
400-2200 OSER AVE. SE DECISION MADE: 12-JAN-07  
HAUPPAUGE, NY 11788 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: AYCAN WORKSTATION OSIRIX

AYCAN DIGITALSYSTEME GMBH 510(k) NO: [K063470](#)<sup>16</sup>(TRADITIONAL)  
ATTN: CARL ALLETTO PHONE NO : 940-300-8601  
1600 MANCHESTER WAY SE DECISION MADE: 05-JAN-07  
CORINTH, TX 76210 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: BWF-5 MEDICAL LASER SERIES, 810 NM; 930 NM; 980 NM; 1080 NM

B&W TEK, INC. 510(k) NO: [K062363](#)<sup>17</sup>(TRADITIONAL)  
ATTN: SEAN WANG PHONE NO : 302-368-7824  
19 SHEA WAY, SUITE 301 SE DECISION MADE: 17-JAN-07  
NEWARK, DE 19713 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: VENATECH LP BRACHIAL INTRODUCER SYSTEM (ANTECUBITAL)

B. BRAUN MEDICAL, INC. 510(k) NO: [K063217](#)<sup>18</sup>(TRADITIONAL)  
ATTN: PAUL O'CONNELL PHONE NO : 847-274-0097  
824 TWELFTH AVE. SE DECISION MADE: 12-JAN-07  
BETHLEHEM, PA 18018 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: IPUMP PAIN MANAGEMENT SYSTEM, MODEL 2L3107, 2L3107K  
BAXTER HEALTHCARE CORP. 510(k) NO: [K052973](#)<sup>19</sup>(TRADITIONAL)  
ATTN: JOHN MANARIK PHONE NO : 847-473-6294  
1620 WAUKEGAN ROAD SE DECISION MADE: 25-JAN-07  
MCGAW PARK, IL 60085-6730 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TRANSDISCAL SYSTEM, MODELS TDP-17-150-6, TDI-17-150, TDA-PPU-1,  
BAYLIS MEDICAL CO., INC. 510(k) NO: [K062937](#)<sup>20</sup>(TRADITIONAL)  
ATTN: MEGHAL KHAKHAR PHONE NO : 905 602 4875  
2580 MATHESON BLVD. E SE DECISION MADE: 08-JAN-07  
MISSISSAUGA, ONTARIO, CANADA L4W 4510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM-CEFTAZIDIME (GN) 0.5-6  
BECTON DICKINSON & CO. 510(k) NO: [K063573](#)<sup>21</sup>(TRADITIONAL)  
ATTN: VICKI KENNEDY WHITLEY PHONE NO : 410-316-4161  
7 LOVETON CIR. SE DECISION MADE: 11-JAN-07  
SPARKS, MD 21152 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM - CEFPODOXIME (GN) 0.12  
BECTON, DICKINSON & CO. 510(k) NO: [K063300](#)<sup>22</sup>(TRADITIONAL)  
ATTN: VICKI K WHITLEY PHONE NO : 410-316-4161  
7 LOVETON CIR. SE DECISION MADE: 29-JAN-07  
SPARKS, MD 21152-0999 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LANDLEX, MODEL S403X  
BESTEAM TECHNOLOGY INC. 510(k) NO: [K063196](#)<sup>23</sup>(TRADITIONAL)  
ATTN: JUNNATA CHANG PHONE NO : 886 4 22465396  
14F-2 NO. 1 LANE 25 SE DECISION MADE: 23-JAN-07  
ZHUANGJING RD. 510(k) SUMMARY AVAILABLE FROM FDA  
BANQIAO, CHINA (TAIWAN) 220

DEVICE: SHARPS CONTAINER, MODEL 039-413  
BIODEX MEDICAL SYSTEMS, INC. 510(k) NO: [K063666](#)<sup>24</sup>(TRADITIONAL)  
ATTN: CLYDE SCHLEIN PHONE NO : 631-924-9000  
20 RAMSAY RD. SE DECISION MADE: 25-JAN-07  
SHIRLEY, NY 11967 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ARCHITECT SHBG REAGENT KIT, ARCHITECT SHBG CALIBRATOR KIT, AND A  
BIOKIT S.A. 510(k) NO: [K060818](#)<sup>25</sup>(TRADITIONAL)  
ATTN: JOAN GUIXER PHONE NO : 349 386 090  
CAN MALE S/N SE DECISION MADE: 23-JAN-07  
LLISSA D'AMUNT 510(k) SUMMARY AVAILABLE FROM FDA  
BARCELONA, SPAIN 08186

DEVICE: EZLASE  
BIOLASE TECHNOLOGY, INC. 510(k) NO: [K061898](#)<sup>26</sup>(TRADITIONAL)  
ATTN: IOANA M RIZOIU PHONE NO : 949-361-1200  
4 CROMWELL SE DECISION MADE: 26-JAN-07  
IRVINE, CA 92618 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: VITEK 2 GRAM POSITIVE AMOXICILLIN FOR STREPTOCOCCUS PNEUMONIAE  
BIOMERIEUX, INC. 510(k) NO: [K063597](#)<sup>27</sup>(TRADITIONAL)  
ATTN: JOLYN TENLLADO PHONE NO : 314-731-8386  
595 ANGLUM RD. SE DECISION MADE: 19-JAN-07  
HAZELWOOD, MO 63042 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: VITEK 2 GRAM POSITIVE MEROPENEM FOR STREPTOCOCCUS PNEUMONIAE  
BIOMERIEUX, INC. 510(k) NO: [K063623](#)<sup>28</sup>(TRADITIONAL)  
ATTN: JOLYN TENLLADO PHONE NO : 314-731-8386  
595 ANGLUM RD. SE DECISION MADE: 11-JAN-07  
HAZELWOOD, MO 63042 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: COMPRESS SEGMENTAL FEMORAL REPLACEMENT SYSTEM (SHORT SPINDLE AND

BIOMET MANUFACTURING CORP. 510(k) NO: [K062998](#)<sup>29</sup>(TRADITIONAL)  
ATTN: JING XIE PHONE NO : 574-267-6639  
PO BOX 587 SE DECISION MADE: 19-JAN-07  
WARSAW, IN 46581-0587 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MICROPLASTY TIBIAL TRAYS

BIOMET MANUFACTURING CORP. 510(k) NO: [K063732](#)<sup>30</sup>(TRADITIONAL)  
ATTN: BECKY EARL PHONE NO : 574-267-6639  
PO BOX 587 SE DECISION MADE: 18-JAN-07  
WARSAW, IN 46581-0587 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TRIAGE PROTEIN C TEST

BIOSITE INCORPORATED 510(k) NO: [K062530](#)<sup>31</sup>(TRADITIONAL)  
ATTN: FIL V BUENVIAJE PHONE NO : 858-805-2722  
9975 SUMMERS RIDGE RD SE DECISION MADE: 29-JAN-07  
SAN DIEGO, CA 92121 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: BIOTOP HOOKSAFE U-100 INSULIN SYRINGE, MODELS 0.5CC/ML AND 1CC/M

BIOTOP TECHNOLOGY CO., LTD. 510(k) NO: [K062318](#)<sup>32</sup>(TRADITIONAL)  
ATTN: LYDIA LEE PHONE NO : 886 2 23957606  
CHUNG-HSIAO E. ROAD, SEC. 2 SE DECISION MADE: 03-JAN-07  
12F-2, NO. 130 510(k) SUMMARY AVAILABLE FROM FDA  
TAIPEI, CHINA (TAIWAN) 100

DEVICE: DUET SYSTEM

BIOVIEW LTD. 510(k) NO: [K061602](#)<sup>33</sup>(TRADITIONAL)  
ATTN: DORIT WINITZ PHONE NO : 972 361 232981  
7 JABOTINSKY ST. SE DECISION MADE: 23-JAN-07  
RAMAT GAN, ISRAEL 52520 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ACE BOND SE

BISCO, INC. 510(k) NO: [K063780](#)<sup>34</sup>(SPECIAL)  
ATTN: BENJAMIN LICHTENWALNER PHONE NO : 847-534-6146  
1100 WEST IRVING PARK RD. SE DECISION MADE: 19-JAN-07  
SCHAUMBURG, IL 60193 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: BONART ART-L3 LED CURING LIGHT

BONART CO. LTD. 510(k) NO: [K062289](#)<sup>35</sup>(TRADITIONAL)  
ATTN: ERIC L ONG PHONE NO : 909-594-8066  
398 S. LEMON CREEK DR. SE DECISION MADE: 03-JAN-07  
STE. L 510(k) STATEMENT  
WALNUT, CA 91789

DEVICE: MODIFICATION TO VECTORVISION TRAUMA

BRAINLAB, AG 510(k) NO: [K062358](#)<sup>36</sup>(SPECIAL)  
ATTN: RAINER BIRKENBACH PHONE NO : 498 999 15680  
KAPELLENSTR. 12 SE DECISION MADE: 17-JAN-07  
FELDKIRCHEN, GERMANY 85622 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: BREAS ISLEEP 20I

BREAS MEDICAL AB 510(k) NO: [K063476](#)<sup>37</sup>(SPECIAL)  
ATTN: KARL-JOHAN HOLM PHONE NO : 46 318 68800  
FORETAGSVAGEN 1 SE DECISION MADE: 22-JAN-07  
MOLNLYCKE, SWEDEN 435 33 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GLASS LOSS OF RESISTANCE SYRINGE

BUSSE HOSPITAL DISPOSABLES, INC. 510(k) NO: [K063018](#)<sup>38</sup>(TRADITIONAL)  
ATTN: MUHAMAD ANSARI PHONE NO : 631-435-4711  
75 ARKAY DR. SE DECISION MADE: 22-JAN-07  
HAUPPAUGE, NY 11788 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: POWERPORT POLYMETRIC PORT WITH 8 FR S/L CHRONOFLEX CATHETER

C.R. BARD, INC. 510(k) NO: [K063377](#)<sup>39</sup>(TRADITIONAL)  
ATTN: MICHAELA RIVKOWICH PHONE NO : 801-595-0700

5425 WEST AMELIA EARHART DR. SE DECISION MADE: 25-JAN-07  
SALT LAKE CITY, UT 84116 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: X-FORCE N30 NEPHROSTOMY BALLOON DILATION CATHETER  
C.R. BARD, INC. 510(k) NO: [K063632](#)<sup>40</sup>(SPECIAL)  
ATTN: TERRI MORRIS PHONE NO : 678-342-4922  
13183 HARLAND DRIVE SE DECISION MADE: 05-JAN-07  
COVINGTON, GA 30014-6421 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CF-1  
CANON, INC. 510(k) NO: [K063717](#)<sup>41</sup>(TRADITIONAL)  
ATTN: SHEILA DRISCOLL PHONE NO : 516-328-5602  
ONE CANON PLAZA SE DECISION MADE: 23-JAN-07  
LAKE SUCCESS, NY 11042-1198 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: CARDICA C-PORT XA DISTAL ANASTOMOSIS SYSTEM  
CARDICA, INC. 510(k) NO: [K063644](#)<sup>42</sup>(SPECIAL)  
ATTN: TIFFINI LALUDE PHONE NO : 650-331-7153  
900 SAGINAW DR. SE DECISION MADE: 11-JAN-07  
REDWOOD CITY, CA 94063 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CIRRUS HD-OCT, MODEL 4000  
CARL ZEISS MEDITEC INC 510(k) NO: [K063378](#)<sup>43</sup>(TRADITIONAL)  
ATTN: JUDITH A BRIMACOMBE PHONE NO : 925-557-4616  
5160 HACIENDA DR. SE DECISION MADE: 26-JAN-07  
DUBLIN, CA 94568 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CATACHEM, INC., BILE ACIDS REAGENTS AND/OR BILE ACIDS TEST KIT  
CATACHEM, INC. 510(k) NO: [K062503](#)<sup>44</sup>(TRADITIONAL)  
ATTN: LUIS P LEON PHONE NO : 203-335-9277  
955 CONNECTICUT AVENUE SE DECISION MADE: 19-JAN-07  
SUITE 4106 510(k) STATEMENT  
BRIDGEPORT, CT 06607

DEVICE: OSTENE, AOC, OSTEOTENE, CERETENE, CEREPOR, APTENE, APATENE, ACTI  
CEREMED INC. 510(k) NO: [K070093](#)<sup>45</sup>(SPECIAL)  
ATTN: TADEUSZ WELLISZ M.D. PHONE NO : 310-815-2125  
3643 LENAWEE AVE. SE DECISION MADE: 24-JAN-07  
LOS ANGELES, CA 90016 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MODIFIED MERCI RETRIEVER, MODEL 90050  
CONCENTRIC MEDICAL, INC. 510(k) NO: [K062046](#)<sup>46</sup>(TRADITIONAL)  
ATTN: KIRSTEN VALLEY PHONE NO : 650-938-2100  
1380 SHOREBIRD WAY SE DECISION MADE: 19-JAN-07  
MOUNTAIN VIEW, CA 94043 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MODIFICATION TO MERCI RETRIEVER, MODELS X5 AND X6  
CONCENTRIC MEDICAL, INC. 510(k) NO: [K063774](#)<sup>47</sup>(SPECIAL)  
ATTN: KIRSTEN VALLEY PHONE NO : 650-938-2100  
1380 SHOREBIRD WAY SE DECISION MADE: 24-JAN-07  
MOUNTAIN VIEW, CA 94043 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CONMED ABC DISSECTING BLADE ELECTRODE, MODEL 139330; BLUNT NEEDL  
CONMED CORPORATION 510(k) NO: [K062082](#)<sup>48</sup>(TRADITIONAL)  
ATTN: SHAWN RIEDEL PHONE NO : 303-269-8224  
14603 E. FREMONT AVE. SE DECISION MADE: 25-JAN-07  
CENTENNIAL, CO 80112 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CONMED LINVATEC 24K IRRIGATION SYSTEM  
CONMED LINVATEC 510(k) NO: [K063326](#)<sup>49</sup>(TRADITIONAL)  
ATTN: SUE F DAUTERMAN PHONE NO : 727-399-5321  
11311 CONCEPT BOULEVARD SE DECISION MADE: 31-JAN-07  
LARGO, FL 33773-4908 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: SYSTEM 83 PLUS MINIFLEX WASHER-DISINFECTOR  
CUSTOM ULTRASONICS 510(k) NO: [K061430](#)<sup>50</sup>(TRADITIONAL)  
ATTN: LAWRENCE F MUSCARELLA PHONE NO : 215-364-1477  
144 RAILROAD DR. SE DECISION MADE: 12-JAN-07  
IVYLAND, PA 18974 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: YAG MIR II LASER  
CYNOSURE, INC. 510(k) NO: [K070063](#)<sup>51</sup>(SPECIAL)  
ATTN: GEORGE CHO PHONE NO : 978-256-4200  
5 CARLISLE ROAD SE DECISION MADE: 30-JAN-07  
WESTFORD, MA 01886 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CYTORI LIPOPLASTY SYSTEM WITH CELASE REAGENT  
CYTORI THERAPEUTICS, INC. 510(k) NO: [K063235](#)<sup>52</sup>(TRADITIONAL)  
ATTN: KENNETH K KLEINHENZ PHONE NO : 858-458-0900  
3020 CALLAN ROAD SE DECISION MADE: 24-JAN-07  
SAN DIEGO, CA 92121-1109 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: 3 SERIES PHOTOTHERAPY CABINET  
DAAVLIN CO. 510(k) NO: [K063621](#)<sup>53</sup>(TRADITIONAL)  
ATTN: TARA MANSUR PHONE NO : 419-636-6304  
205 WEST BEMENT ST. SE DECISION MADE: 17-JAN-07  
P.O. BOX 626 510(k) SUMMARY AVAILABLE FROM FDA  
BRYAN, OH 43506

DEVICE: DIMENSION VISTA B2MIC FLEX REAGENT CARTRIDGE, PROTEIN 1 CALIBRAT  
DADE BEHRING, INC. 510(k) NO: [K063272](#)<sup>54</sup>(TRADITIONAL)  
ATTN: KATHLEEN DRAY-LYONS PHONE NO : 781-826-4551  
P.O. BOX 6101 SE DECISION MADE: 26-JAN-07  
NEWARK,, DE 19714 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DIMENSION VISTA TRF FLEX REAGENT CARTRIDGE, PROTEIN 1 CALIBRATOR  
DADE BEHRING, INC. 510(k) NO: [K063322](#)<sup>55</sup>(TRADITIONAL)  
ATTN: KATHLEEN DRAY-LYONS PHONE NO : 781-826-4551  
GLASGOW SITE, PO BOX 6101 SE DECISION MADE: 24-JAN-07  
NEWARK, DE 19714-6101 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DIMENSION VISTA CYSC FLEX REAGENT CARTRIDGE, PROTEIN 3 CALIBRATO  
DADE BEHRING, INC. 510(k) NO: [K063351](#)<sup>56</sup>(TRADITIONAL)  
ATTN: KATHLEEN A DRAY-LYONS PHONE NO : 781-826-4551  
P.O. BOX 6101 SE DECISION MADE: 22-JAN-07  
NEWARK,, DE 19714 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DIMENSION VISTA PROTEIN 1 CALIBRATOR AND CONTROL L, M, H; PROTEI  
DADE BEHRING, INC. 510(k) NO: [K063508](#)<sup>57</sup>(TRADITIONAL)  
ATTN: HELEN M LEE PHONE NO : 302-631-8706  
P.O. BOX 6101 SE DECISION MADE: 23-JAN-07  
NEWARK,, DE 19714 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DIMENSION VISTA A1AT FLEX REAGENT CARTRIDGE AND PROTEIN 1 CALIBR  
DADE BEHRING, INC. 510(k) NO: [K063610](#)<sup>58</sup>(TRADITIONAL)  
ATTN: KATHLEEN DRAY-LYONS PHONE NO : 781-826-4551  
P.O. BOX 6101 SE DECISION MADE: 11-JAN-07  
NEWARK,, DE 19714 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DATASCOPE FIBER OPTIC PRESSURE SENSOR INTRA-AORTIC BALLOON CATHE  
DATASCOPE CORP. 510(k) NO: [K063525](#)<sup>59</sup>(SPECIAL)  
ATTN: NANCY COHEN PHONE NO : 973-244-6104  
15 LAW DR. SE DECISION MADE: 05-JAN-07  
FAIRFIELD, NJ 07004-0011 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PHASE 3, MODEL DT-1  
DATREND SYSTEMS, INC. 510(k) NO: [K062099](#)<sup>60</sup>(TRADITIONAL)





EUGENE, OR 97405 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: HUMAPEN LUXURA HD  
ELI LILLY AND CO. 510(k) NO: [K063151](#)<sup>71</sup>(TRADITIONAL)  
ATTN: LEEANN CHAMBERS PHONE NO : 317-277-1813  
LILLY CORPORATE CENTER SE DECISION MADE: 09-JAN-07  
INDIANAPOLIS, IN 46285 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: SELECT TENS, MODEL 4600S  
EMPI 510(k) NO: [K061650](#)<sup>72</sup>(TRADITIONAL)  
ATTN: CARL BEAURLINE PHONE NO : 651-389-0771  
599 CARDIGAN RD. SE DECISION MADE: 22-JAN-07  
ST. PAUL, MN 55126 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: VECTRA GENISYS VMS FR  
ENCORE MEDICAL, L.P. 510(k) NO: [K062354](#)<sup>73</sup>(TRADITIONAL)  
ATTN: MICHAEL TREAS PHONE NO : 423-870-2281  
4717 ADAMS ROAD SE DECISION MADE: 26-JAN-07  
HIKSON, TN 37343 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ENCORE KNEE SYSTEM IFU  
ENCORE MEDICAL, L.P. 510(k) NO: [K063406](#)<sup>74</sup>(TRADITIONAL)  
ATTN: TEFFANY HUTTO PHONE NO : 512-834-6225  
9800 METRIC BLVD. SE DECISION MADE: 08-JAN-07  
AUSTIN, TX 78758 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ERBE MONOPOLAR ATTACHMENT FOR HELIX HYDRO-JET, MODEL P/N 20139-0  
ERBE USA, INC. 510(k) NO: [K062712](#)<sup>75</sup>(TRADITIONAL)  
ATTN: JOHN TARTAL PHONE NO : 770-955-4400  
2225 NORTHWEST PKWY. SE DECISION MADE: 26-JAN-07  
MARIETTA, GA 30067 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: HARMONIC FOCUS CURVED SHEARS AND TORQUE WRENCH, HARMONIC BLUE HA  
ETHICON ENDO-SURGERY, LLC 510(k) NO: [K063192](#)<sup>76</sup>(TRADITIONAL)  
ATTN: ELIZABETH MILLER, MST PHONE NO : 513-337-7146  
4545 CREEK ROAD SE DECISION MADE: 30-JAN-07  
CINCINNATI, OH 45242 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: EUSURE, EUGLUCO  
EUMED BIOTECHNOLOGY CO., LTD. 510(k) NO: [K062892](#)<sup>77</sup>(TRADITIONAL)  
ATTN: KE-MIN JEN PHONE NO : 886 3 5208829  
NO. 58, FU-CHIUN ST. SE DECISION MADE: 22-JAN-07  
HSIN CHU CITY, CHINA (TAIWAN) 300 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: SPIDERFX EMBOLIC PROTECTION DEVICE  
EV3 INC 510(k) NO: [K063785](#)<sup>78</sup>(SPECIAL)  
ATTN: DAVID WORRELL PHONE NO : 763-398-7000  
9600 54TH AVENUE NORTH SE DECISION MADE: 19-JAN-07  
PLYMOUTH, MN 55442-2111 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LOCOBASE WOUND AND SKIN EMULSION  
FERNDAL LABORATORIES, INC. 510(k) NO: [K060272](#)<sup>79</sup>(TRADITIONAL)  
ATTN: RICHARD A HAMER PHONE NO : 248-548-0900  
780 WEST EIGHT MILE RD. SE DECISION MADE: 12-JAN-07  
FERNDAL, MI 48220 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: THE CROSSER CATHETER, MODEL CR1100 AND SYSTEM ELECTRONICS, MODEL  
FLOWCARDIA INC 510(k) NO: [K062868](#)<sup>80</sup>(TRADITIONAL)  
ATTN: DUSTIN MICHAELS PHONE NO : 408-617-0352  
745 N. PASTORIA AVE. SE DECISION MADE: 19-JAN-07  
SUNNYVALE, CA 94085 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GAMBRO QUICKSET BLOODLINES  
GAMBRO RENAL PRODUCTS 510(k) NO: [K063290](#)<sup>81</sup>(TRADITIONAL)



ATTN: THOMAS B DOWELL                      PHONE NO : 303-231-4094  
10810 WEST COLLINS AVE.                   SE DECISION MADE: 30-JAN-07  
LAKEWOOD, CO 80215                       510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GAMBRO POSICLEAR  
GAMBRO SERVICES, INC.                      510(k) NO: [K061782](#)<sup>82</sup>(TRADITIONAL)  
ATTN: JEFFERY R SHIDEMAN                 PHONE NO : 952-835-4018  
7307 GLOUCHESTER DRIVE                   SE DECISION MADE: 04-JAN-07  
EDINA, MN 55435                           510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GEMORE REUSEABLE SELF ADHESIVE ELECTRODE, MODELS WIRE SERIES, SN  
GEMORE TECHNOLOGY CO., LTD.              510(k) NO: [K062675](#)<sup>83</sup>(TRADITIONAL)  
ATTN: TONY C.S. CHANG                    PHONE NO : 886 2 88091799  
11 FL, NO. 29-5, SEC. 2                   SE DECISION MADE: 04-JAN-07  
CHUNG CHENG E. RD.                       510(k) SUMMARY AVAILABLE FROM FDA  
TAN SHUI, TAIPEI HSIEN, CHINA (TAIWAN) 251

DEVICE: GEN-PROBE APTIMA ASSAY FOR CHLAMYDIA TRACHOMATIS, MODEL 1199  
GEN-PROBE, INC.                           510(k) NO: [K063451](#)<sup>84</sup>(TRADITIONAL)  
ATTN: E. JOSEPH MCMULLEN                PHONE NO : 858-410-8649  
10210 GENETIC CENTER DR.                 SE DECISION MADE: 22-JAN-07  
SAN DIEGO, CA 92121-4362                 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GEN-PROBE APTIMA ASSAY FOR NEISSERIA GONORRHOEAE MODEL#1091  
GEN-PROBE, INC.                           510(k) NO: [K063664](#)<sup>85</sup>(TRADITIONAL)  
ATTN: E. JOSEPH MCMULLEN                PHONE NO : 858-410-8649  
10210 GENETIC CENTER DR.                 SE DECISION MADE: 25-JAN-07  
SAN DIEGO, CA 92121-4362                 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GMD UNIVERSAL CIRCUMCISION CLAMP, MODEL 200  
GENERIC MEDICAL DEVICE, INC.             510(k) NO: [K063429](#)<sup>86</sup>(TRADITIONAL)  
ATTN: MONICA MONTANEZ                   PHONE NO : 713-523-9630  
3906 ROSELAND ST.                         SE DECISION MADE: 17-JAN-07  
HOUSTON, TX 77006                         510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PORTABLE X-RAY SYSTEM, MODEL PORT-X II  
GENORAY CO., LTD.                         510(k) NO: [K063121](#)<sup>87</sup>(TRADITIONAL)  
ATTN: CHARLIE MACK                       PHONE NO : 931-937-8093  
340 SHADY GROVE ROAD                     SE DECISION MADE: 11-JAN-07  
FLINTVILLE, TN 37335                     510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: SEPRAMESH, MODEL 5959-1214  
GENZYME CORPORATION                      510(k) NO: [K063739](#)<sup>88</sup>(TRADITIONAL)  
ATTN: MATTHEW HIBBERT                   PHONE NO : 617-374-7463  
500 KENDALL STREET                       SE DECISION MADE: 17-JAN-07  
CAMBRIDGE, MA 02142                      510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: GSO BONE FIXATION FASTENERS  
GOLD STANDARD ORTHOPAEDICS LLC          510(k) NO: [K063589](#)<sup>89</sup>(TRADITIONAL)  
ATTN: DAVID BAUGHMAN                    PHONE NO : 502-581-8770  
1226 WEST ROWAN ST.                      SE DECISION MADE: 31-JAN-07  
LOUISVILLE, KY 40203                   510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: RAPIDTEG TEG-ACT TEST  
HAEMOSCOPE CORP.                         510(k) NO: [K062604](#)<sup>90</sup>(TRADITIONAL)  
ATTN: ELI COHEN                          PHONE NO : 847-588-0453  
6231 W. HOWARD ST.                       SE DECISION MADE: 31-JAN-07  
NILES, IL 60714                           510(k) STATEMENT

DEVICE: 36MM COCR FEMORAL HEAD AND 36MM ACETABULAR INSERT  
HAYES MEDICAL, INC.                      510(k) NO: [K070061](#)<sup>91</sup>(SPECIAL)  
ATTN: LUKE ROSE                          PHONE NO : 916-355-7156

1115 WINDFIELD WAY, SUITE 100 SE DECISION MADE: 31-JAN-07  
EL DORADO HILLS, CA 95762-9623 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: POWDER FREE NITRILE EXAMINATION GLOVES (WHITE AND BLUE COLOR)  
HL RUBBER INDUSTRIES SDN BHD 510(k) NO: [K063524](#)<sup>92</sup>(TRADITIONAL)  
ATTN: KENNY HOE PHONE NO : 606 481 1088  
LOT 10, KAWASAN SE DECISION MADE: 23-JAN-07  
PERINDUSTRIAN DIOH 510(k) STATEMENT  
KUALA PILAH, NEGERI SEMBILAN, MALAYSIA 72000

DEVICE: TRIATHLON CS (CONDYLAR STABILIZING) LIPPED INSERT  
HOWMEDICA OSTEONICS 510(k) NO: [K063423](#)<sup>93</sup>(TRADITIONAL)  
ATTN: SHERYL R BAGALIO PHONE NO : 201-831-5581  
325 CORPORATE DRIVE SE DECISION MADE: 22-JAN-07  
MAHWAH, NJ 07430 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: REVLITE C6 Q-SWITCHED ND:YAG LASER SYSTEM  
HOYA CONBIO, INC 510(k) NO: [K063834](#)<sup>94</sup>(SPECIAL)  
ATTN: DONNA TEMPLEMAN PHONE NO : 925-846-0458  
1105 SUNSET CREEK LANE SE DECISION MADE: 25-JAN-07  
PLEASANTON, CA 94566 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: FLIGHT DENTAL SYSTEMS A-SERIES DENTAL OPERATIVE UNIT  
HR DENTAL PRODUCTS INC 510(k) NO: [K070196](#)<sup>95</sup>(TRADITIONAL)  
ATTN: JIM RONALDS PHONE NO : 905 799 0517  
21 KENVIEW BLVD, UNIT 9 SE DECISION MADE: 26-JAN-07  
BRAMPTON, ONTARIO, CANADA L6T 5G7 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: ON-Q, PAINBUSTER, C-BLOC, SELECT-A-FLOW, ONDEMAND, HOME PUMP, ECL  
I-FLOW CORP. 510(k) NO: [K063530](#)<sup>96</sup>(SPECIAL)  
ATTN: JAMES J DAL PORTO PHONE NO : 949-206-2700  
20202 WINDROW DR. SE DECISION MADE: 26-JAN-07  
LAKE FOREST, CA 92630 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: IKONISCOPE ONCOFISH BLADDER TEST SYSTEM  
IKONISYS INC 510(k) NO: [K062755](#)<sup>97</sup>(TRADITIONAL)  
ATTN: OSCAR SANCHEZ PHONE NO : 203-776-0791  
5 SCIENCE PARK SE DECISION MADE: 04-JAN-07  
NEW HAVEN, CT 06511 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: X3C DIGITAL RADIOGRAPHIC DETECTOR  
IMAGING DYNAMICS COMPANY LTD. 510(k) NO: [K070079](#)<sup>98</sup>(SPECIAL)  
ATTN: SHIRANTHAN SAMARAPPULI PHONE NO : 403 251 9939  
2340 PEGASUS WAY, NE SE DECISION MADE: 31-JAN-07  
SUITE 151 510(k) SUMMARY AVAILABLE FROM FDA  
CALGARY, CANADA T2E 8M5

DEVICE: IMC-HEARTWAY, LLC ELECTRIC WHEELCHAIR, MODEL TIARA (P4AS)  
IMC-HEARTWAY, LLC 510(k) NO: [K063475](#)<sup>99</sup>(ABBREVIATED)  
ATTN: MICHAEL CHEN PHONE NO : 866-464-9779  
6140 MID METRO DRIVE, SUITE 6 SE DECISION MADE: 23-JAN-07  
FORT MYERS, FL 33912 510(k) STATEMENT

DEVICE: INION CPS/OTPS FREEDOMPLATE  
INION OY 510(k) NO: [K063410](#)<sup>100</sup>(TRADITIONAL)  
ATTN: KATI MARTTINEN PHONE NO : 358 323 06600  
LAAKARINKATU 2 SE DECISION MADE: 23-JAN-07  
TAMPERE, FINLAND 33520 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PARAMOUNT VBR SYSTEM  
INNOVATIVE SPINAL TECHNOLOGIES INC 510(k) NO: [K062759](#)<sup>101</sup>(TRADITIONAL)  
ATTN: GINA YEH PHONE NO : 508-452-3520  
111FORBES BLVD SE DECISION MADE: 12-JAN-07

MANSFIELD, MA 02048

510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: INOVEL HEALTH CARE N95 PARTICULATE RESPIRATORS AND SURGICAL MASK

INOVEL LLC 510(k) NO: [K063747](#)<sup>102</sup>(TRADITIONAL)  
ATTN: WILLIAM WARZYNIAK PHONE NO : 866-546-6835  
10111 W. JEFFERSON BLVD. SE DECISION MADE: 12-JAN-07  
CULVER CITY, CA 90232-3509 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: ULTRACLIP II WING AND ULTRACLIP II COIL

INRAD 510(k) NO: [K063238](#)<sup>103</sup>(TRADITIONAL)  
ATTN: MELISSA LALOMIA PHONE NO : 800-558-4647  
4375 DONKER COURT S.E. SE DECISION MADE: 30-JAN-07  
KENTWOOD, MI 49512 510(k) STATEMENT

DEVICE: VOLUMETRIC TOMOGRAPHY

INSTRUMENTARIUM DENTAL INC. 510(k) NO: [K063773](#)<sup>104</sup>(TRADITIONAL)  
ATTN: FRANK KASHINSKI PHONE NO : 414-747-6315  
300 WEST EDGERTON AVE. SE DECISION MADE: 31-JAN-07  
MILWAUKEE, WI 53207-6025 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ACL TOP

INSTRUMENTATION LABORATORY CO. 510(k) NO: [K063679](#)<sup>105</sup>(SPECIAL)  
ATTN: CAROL MARBLE PHONE NO : 781-861-4467  
113 HARTWELL AVE. SE DECISION MADE: 12-JAN-07  
LEXINGTON, MA 02421 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: INTEGRA MOZAIK BONE REGENERATION MATRIX - STRIPS

INTEGRA LIFESCIENCES CORP. 510(k) NO: [K063124](#)<sup>106</sup>(TRADITIONAL)  
ATTN: DIANA M BORDON PHONE NO : 609-936-2240  
311 ENTERPRISE DRIVE SE DECISION MADE: 19-JAN-07  
PLAINSBORO, NJ 08536 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: INTELEPACS

INTELERAD MEDICAL SYSTEMS INC. 510(k) NO: [K070080](#)<sup>107</sup>(TRADITIONAL)  
ATTN: ANIBAL JODORCOVSKY PHONE NO : 514 931 6222  
460 STE-CATHERINE WEST SE DECISION MADE: 24-JAN-07  
SUITE 210 510(k) SUMMARY AVAILABLE FROM FDA  
MONTREAL QUEBEC, CANADA M3B 1A7 THIRD PARTY REVIEW

DEVICE: PENCURE, MODEL VL-7

J. MORITA USA, INC. 510(k) NO: [K063529](#)<sup>108</sup>(TRADITIONAL)  
ATTN: ROBERT A SILVERMAN PHONE NO : 202-783-5070  
1425 K STREET NW SE DECISION MADE: 05-JAN-07  
SUITE 1100 510(k) SUMMARY AVAILABLE FROM FDA  
WASHINGTON, DC 20005

DEVICE: POWERTONE, MODEL PT-11

JOHARI DIGITAL HEALTHCARE, LTD. 510(k) NO: [K062439](#)<sup>109</sup>(TRADITIONAL)  
ATTN: NISHA JOHARI PHONE NO : 818-878-9291  
26540 W. AGOURA ROAD SE DECISION MADE: 08-JAN-07  
SUITE 230 510(k) SUMMARY AVAILABLE FROM FDA  
CALABASES, CA 91302

DEVICE: FEMORAL INTRAFIX SCREW AND SHEATH

JOHNSON & JOHNSON COMPANY 510(k) NO: [K063577](#)<sup>110</sup>(TRADITIONAL)  
ATTN: RUTH FORSTADT PHONE NO : 508-977-3988  
325 PARAMOUNT DRIVE SE DECISION MADE: 25-JAN-07  
RAYNHAM, MA 02767 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: KARL STORZ FLEXIBLE VIDEO-URETHRO-CYSTOSCOPE SYSTEM

KARL STORZ ENDOSCOPY-AMERICA, INC. 510(k) NO: [K062918](#)<sup>111</sup>(TRADITIONAL)  
ATTN: SUSIE CHEN PHONE NO : 310-348-4201  
600 CORPORATE POINTE SE DECISION MADE: 17-JAN-07

5TH FLOOR  
CULVER CITY, CA 90230-7600

510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: KARL STORZ VIDEO LOWER G.I. ENDOSCOPE SYSTEM  
KARL STORZ ENDOSCOPY-AMERICA, INC. 510(k) NO: [K063585](#)<sup>112</sup>(TRADITIONAL)  
ATTN: SUSIE CHEN PHONE NO : 310-338-8100  
600 CORPORATE POINTE SE DECISION MADE: 31-JAN-07  
CULVER CITY, CA 90230-7600 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: V.A.C. FREEDOM CANISTER, MODEL M6275421; V.A.C. ATS CANISTER, MO  
KCI USA, INC. 510(k) NO: [K063590](#)<sup>113</sup>(SPECIAL)  
ATTN: CHRISTY HUBBARD OVIATT PHONE NO : 210-255-6105  
8023 VANTAGE DR. SE DECISION MADE: 25-JAN-07  
SAN ANTONIO, TX 78230-4726 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ENDOGUIDE  
KMS MEDICAL LLC 510(k) NO: [K063654](#)<sup>114</sup>(TRADITIONAL)  
ATTN: MARIO ARBESU PHONE NO : 305-266-3388  
7290 SW 42ND STREET SE DECISION MADE: 31-JAN-07  
MIAMI, FL 33155 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: URGOCELL AG ANTIMICROBIAL WOUND DRESSING WITH SILVER  
LABORATOIRES URGO 510(k) NO: [K062559](#)<sup>115</sup>(TRADITIONAL)  
ATTN: SOPHIE FORTIN PHONE NO : 33 3 80447967  
42, RUE DE LONGVIC SE DECISION MADE: 29-JAN-07  
CHENOVE, FRANCE 21300 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: VELURE FAMILY OF DIODE LASERS AND DELIVERY DEVICE ACCESSORIES  
LASERING S.R.L. 510(k) NO: [K063396](#)<sup>116</sup>(TRADITIONAL)  
ATTN: ALLEN R HOWES PHONE NO : 925-355-0750  
2246 CAMINO RAMON SE DECISION MADE: 17-JAN-07  
SAN RAMON, CA 94583 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MODIFICATION TO EASYSPINE SYSTEM  
LDR SPINE USA 510(k) NO: [K063794](#)<sup>117</sup>(SPECIAL)  
ATTN: FLOYD G LARSON PHONE NO : 858-792-1235  
11234 EL CAMINO REAL SE DECISION MADE: 24-JAN-07  
SUITE 200 510(k) SUMMARY AVAILABLE FROM FDA  
SAN DIEGO, CA 92130

DEVICE: HAIRMAX LASERCOMB  
LEXINGTON INTERNATIONAL, LLC 510(k) NO: [K060305](#)<sup>118</sup>(TRADITIONAL)  
ATTN: EDWARD BASILE PHONE NO : 202-626-2903  
1700 PENNSYLVANIA AVENUE, NW SE DECISION MADE: 18-JAN-07  
WASHINGTON, DC 20006 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: INSUFLOW DEVICE, MODEL 6198  
LEXION MEDICAL, LLC. 510(k) NO: [K063546](#)<sup>119</sup>(SPECIAL)  
ATTN: DUANE LLOYD PHONE NO : 651-635-0000  
5000 TOWNSHIP PKWY SE DECISION MADE: 10-JAN-07  
ST. PAUL, MN 55110 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PILOT SPINAL SYSTEM  
LIFE SPINE 510(k) NO: [K063601](#)<sup>120</sup>(TRADITIONAL)  
ATTN: REBECCA M BROOKS PHONE NO : 847-884-6117  
2400 HASSELL ROAD SE DECISION MADE: 25-JAN-07  
SUITE 370 510(k) SUMMARY AVAILABLE FROM FDA  
HOFFMAN ESTATES, IL 60169

DEVICE: LIFECELL DURAL SUBSTITUTE MATRIX  
LIFECELL CORP. 510(k) NO: [K061208](#)<sup>121</sup>(TRADITIONAL)  
ATTN: REY LIBROJO PHONE NO : 908-947-1114  
ONE MILLENIUM WAY SE DECISION MADE: 03-JAN-07  
BRANCHBURG, NJ 08876 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: K-Y BRAND TOUCH MASSAGE 2-IN-1 TINGLING

MCNEIL-PPC, INC. 510(k) NO: [K062535](#)<sup>122</sup>(TRADITIONAL)  
ATTN: NADER FOTOUHI PH.D. PHONE NO : 908-904-3730  
199 GRANDVIEW RD. SE DECISION MADE: 26-JAN-07  
SKILLMAN, NJ 08558 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ULTRASONIC BIOMETER/PACHYMETER FOR OPHTHALMOLOGY ODM 2100 AND ODM

MEDA LTD. 510(k) NO: [K063433](#)<sup>123</sup>(TRADITIONAL)  
ATTN: EDWARD A KROLL PHONE NO : 440-546-9810  
5905 FAWN LANE SE DECISION MADE: 29-JAN-07  
CLEVELAND, OH 44141 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ULTRASONIC BIOMETER/ PACHYMETER FOR OPHTHALMOLOGY, MODEL ODM 210

MEDA LTD. 510(k) NO: [K063472](#)<sup>124</sup>(TRADITIONAL)  
ATTN: EDWARD A KROLL PHONE NO : 440-546-9810  
5905 FAWN LN. SE DECISION MADE: 31-JAN-07  
CLEVELAND, OH 44141 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: AG-EDGE, MODEL 91200

MEDEL S.P.A. 510(k) NO: [K063103](#)<sup>125</sup>(ABBREVIATED)  
ATTN: TERRENCE O'BRIEN PHONE NO : 919-468-9552  
112 CAVISTON WAY SE DECISION MADE: 08-JAN-07  
CARY, NC 27519 510(k) STATEMENT

DEVICE: SONOTIP II ULTRASOUND NEEDLE SYSTEM

MEDI-GLOBE CORPORATION 510(k) NO: [K070129](#)<sup>126</sup>(TRADITIONAL)  
ATTN: SCOTT KARLER PHONE NO : 650-463-2900  
110 WEST ORION #136 SE DECISION MADE: 31-JAN-07  
TEMPE, AZ 85283 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: BEAMAX

MEDIC SHARPLIGHT LTD. 510(k) NO: [K063249](#)<sup>127</sup>(TRADITIONAL)  
ATTN: DAN LAOR PHONE NO : 972 4 8246632  
6 SIRENI STREET SE DECISION MADE: 17-JAN-07  
HAIFA, ISRAEL 32972 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CLICKZIP, MODEL U-100 INSULIN SAFETY SYRINGE

MEDICAL DEVICE MANUFACTURER (THAIL) 510(k) NO: [K062780](#)<sup>128</sup>(ABBREVIATED)  
ATTN: OYTIP KUNWUNLOP PHONE NO : 661 844 7959  
7/145 MOO 4 SE DECISION MADE: 05-JAN-07  
AMATA CITY INDUSTRIAL ESTATE 510(k) SUMMARY AVAILABLE FROM FDA  
RAYONG, THAILAND 21140

DEVICE: LUMINEX LL LASER SYSTEM

MEDICAL LASER SYSTEMS INC 510(k) NO: [K063574](#)<sup>129</sup>(TRADITIONAL)  
ATTN: MIKI KOLTON PHONE NO : 202-331-3134  
800 CONNECTICUT AVE. NW SE DECISION MADE: 29-JAN-07  
SUITE 500 510(k) SUMMARY AVAILABLE FROM FDA  
WAHINGTON, DC 20006

DEVICE: APEXNRG XFR

MEDICNRG LTD. 510(k) NO: [K063843](#)<sup>130</sup>(SPECIAL)  
ATTN: GEORGE J HATTUB PHONE NO : 508-479-6116  
291 HILLSIDE AVE. SE DECISION MADE: 03-JAN-07  
SOMERSET, MA 02726 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: C-JAWS CERVICAL COMPRESSIVE MINI FRAME

MEDICREA TECHNOLOGIES 510(k) NO: [K062181](#)<sup>131</sup>(TRADITIONAL)  
ATTN: J.D. WEBB PHONE NO : 512-388-0199  
1001 OAKWOOD BLVD. SE DECISION MADE: 16-JAN-07  
ROUND ROCK, TX 78681 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ACTIM PROM AND CONTROLS

MEDIX BIOCHEMICA 510(k) NO: [K061886](#)<sup>132</sup>(TRADITIONAL)  
ATTN: CYNTHIA SINCLAIR PHONE NO : 508-643-0434  
49 PLAIN STREET SE DECISION MADE: 25-JAN-07  
NORTH ATTLEBORO, MA 02760 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LAPMAN LAPAROSCOPE MANIPULATOR AND ACCESSORIES, MODEL 900-200 SE

MEDSYS, S.A. 510(k) NO: [K062968](#)<sup>133</sup>(SPECIAL)  
ATTN: JEFF MORGAN PHONE NO : 253-535-9369  
13723 DANA LN. EAST SE DECISION MADE: 03-JAN-07  
PUYALLUP, WA 98373 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LIFEPAK 12 DEFIBRILLATOR/MONITOR

MEDTRONIC EMERGENCY RESPONSE SYSTEMS 510(k) NO: [K063510](#)<sup>134</sup>(SPECIAL)  
ATTN: MICHELLE ACKERMANN PHONE NO : 425-867-4744  
11811 WILLOWS RD., N.E. SE DECISION MADE: 26-JAN-07  
P.O. BOX 97006 510(k) SUMMARY AVAILABLE FROM FDA  
REDMOND, WA 98073-9706

DEVICE: MODIFICATION TO: SATELLITE SPINAL SYSTEM

MEDTRONIC SOFAMOR DANEK 510(k) NO: [K060415](#)<sup>135</sup>(TRADITIONAL)  
ATTN: RICHARD TREHARNE PHONE NO : 219-396-3133  
1800 PYRAMID PLACE SE DECISION MADE: 05-JAN-07  
MEMPHIS, TN 38132 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MODIFICATION TO CD HORIZON SPINAL SYSTEM

MEDTRONIC SOFAMOR DANEK 510(k) NO: [K063417](#)<sup>136</sup>(SPECIAL)  
ATTN: LEE GRANT PHONE NO : 901-396-3133  
1800 PYRAMID PLACE SE DECISION MADE: 18-JAN-07  
MEMPHIS, TN 38132 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MERETE BLP SMALL FRAGMENT LOCKING BONE PLATE

MERETE MEDICAL GMBH 510(k) NO: [K063487](#)<sup>137</sup>(TRADITIONAL)  
ATTN: DONNA COLEMAN PHONE NO : 914-967-1532  
49 PURCHASE STREET SE DECISION MADE: 22-JAN-07  
RYE, NY 10580 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: SOCK IT! ORAL PAIN GEL

MERLIN GROUP DBA MCMERLIN DENTAL 510(k) NO: [K063148](#)<sup>138</sup>(TRADITIONAL)  
ATTN: EILEEN VENNUM PHONE NO : 972-602-3746  
1610 W. POLO RD SE DECISION MADE: 17-JAN-07  
SUITE A 510(k) SUMMARY AVAILABLE FROM FDA  
GRAND PRAIRIE, TX 75052

DEVICE: TENDER FIBER

MICERIUM S.P.A. 510(k) NO: [K063170](#)<sup>139</sup>(TRADITIONAL)  
ATTN: EUGENIO MICELI PHONE NO : 39 018 57887870  
VIA MARCONI 83 SE DECISION MADE: 12-JAN-07  
AVENGO, ITALY 16030 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MICROTEK MEDICAL SURGICAL GOWN/TOGA

MICROTEK MEDICAL, INC. 510(k) NO: [K062899](#)<sup>140</sup>(TRADITIONAL)  
ATTN: THOMAS BONNER PHONE NO : 800-844-0988  
512 LEHMBERG RD. SE DECISION MADE: 25-JAN-07  
COLUMBUS, MS 39702 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MICRUS MICROCOIL SYSTEM, "CASHMERE" MODEL SRC

MICRUS ENDOVASCULAR CORPORATION 510(k) NO: [K063653](#)<sup>141</sup>(SPECIAL)  
ATTN: PATRICK LEE PHONE NO : 408-433-1400  
821 FOX LANE SE DECISION MADE: 17-JAN-07  
SAN JOSE, CA 95131 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: HEARID+TE TRANSIENT-EVOKED OTOACOUSTIC EMISSIONS ANALYZER

MIMOSA ACOUSTICS, INC. 510(k) NO: [K063338](#)<sup>142</sup>(TRADITIONAL)

ATTN: PATRICIA S JENG                      PHONE NO : 217-367-9740  
60 HAZELWOOD DR., SUITE #209            SE DECISION MADE: 04-JAN-07  
CHAMPAIGN, IL 61820                      510(k) STATEMENT

DEVICE: MEPILEX AG ABSORBENT SILICONE-COATED DRESSING  
MOLNLYCKE HEALTH CARE                   510(k) NO: [K061554](#)<sup>143</sup>(TRADITIONAL)  
ATTN: STEVEN DOWDLEY                    PHONE NO : 678-250-7930  
5550 PEACHTREE PARKWAY                 SE DECISION MADE: 25-JAN-07  
SUITE 500                                 510(k) SUMMARY AVAILABLE FROM FDA  
NORCROSS, GA 30092

DEVICE: MOORLDLS LASER DOPPLER LINE SCANNER  
MOOR INSTRUMENTS LTD.                   510(k) NO: [K063561](#)<sup>144</sup>(TRADITIONAL)  
ATTN: XIABING HUANG                     PHONE NO : 44 129 735715  
MILLWEY                                 SE DECISION MADE: 19-JAN-07  
AXMINSTER, DEVON, UNITED KINGDOM E510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MOORFLPI FULL-FIELD LASER PERFUSION IMAGER  
MOOR INSTRUMENTS LTD.                   510(k) NO: [K063586](#)<sup>145</sup>(TRADITIONAL)  
ATTN: XIABING HUANG                     PHONE NO : 44 129 735715  
MILLWEY                                 SE DECISION MADE: 25-JAN-07  
AXMINSTER, DEVON, UNITED KINGDOM E510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MEDICAL IMAGE MANAGEMENT DEVICES FOR VISION TOOLS  
MTD, INC.                                 510(k) NO: [K063439](#)<sup>146</sup>(TRADITIONAL)  
ATTN: CHRISTINE NICHOLS                 PHONE NO : 973-726-7679  
8 CROWNVIEW COURT                       SE DECISION MADE: 22-JAN-07  
SPARTA, NJ 07871                         510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: NEATSTITCH NEATCLOSE SUTURING DEVICE  
NEAT STITCH LTD.                         510(k) NO: [K063462](#)<sup>147</sup>(TRADITIONAL)  
ATTN: YOSSI MUNCHEER, PH.D.             PHONE NO : 972 462 62876  
HAHADAS 1 ST                             SE DECISION MADE: 12-JAN-07  
OR AKIVA, ISRAEL 30600                 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: NIPRO SAFETOUCH II GAMMA  
NIPRO MEDICAL CORP.                     510(k) NO: [K063721](#)<sup>148</sup>(SPECIAL)  
ATTN: JESSICA OSWALD                     PHONE NO : 305-599-7174  
3150 NW 107 AVE..                       SE DECISION MADE: 12-JAN-07  
MIAMI, FL 33172                         510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: SFB AND CFB IMPLANTS - 5.0 PLATFORM  
NOBEL BIOCARE AB                         510(k) NO: [K063718](#)<sup>149</sup>(SPECIAL)  
ATTN: HERBERT CRANE                     PHONE NO : 714-282-5074  
22715 SAVI RANCH PKWY.                 SE DECISION MADE: 05-JAN-07  
YORBA LINDA, CA 92887                 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: NORDIC IMAGE CONTROL AND EVALUATION (NICE) SOFTWARE, VERSION 2.1  
NORDICICEMEDICAL AS                     510(k) NO: [K063539](#)<sup>150</sup>(TRADITIONAL)  
ATTN: JAMES W KNOX                     PHONE NO : 508-643-0434  
49 PLAIN ST.                             SE DECISION MADE: 17-JAN-07  
NORTH ATTLEBORO, MA 02760             510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: NEUTRON THERAPY SYSTEM  
NORTHERN ILLINOIS UNIV. OUTREACH       510(k) NO: [K063691](#)<sup>151</sup>(TRADITIONAL)  
ATTN: JONATHAN S KAHAN                 PHONE NO : 202-637-5794  
555 THIRTEENTH ST., NW                 SE DECISION MADE: 31-JAN-07  
WASHINGTON, DC 20004                 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: NOVA STATSTRIP GLUCOSE HOSPITAL METER SYSTEM  
NOVA BIOMEDICAL CORP.                   510(k) NO: [K063821](#)<sup>152</sup>(TRADITIONAL)  
ATTN: PAUL W MACDONALD, PHD             PHONE NO : 781-894-0800  
200 PROSPECT ST.                        SE DECISION MADE: 24-JAN-07  
WALTHAM, MA 02454-9141                 510(k) STATEMENT



## DEVICE: SPY IMAGING SYSTEM

NOVADAQ TECHNOLOGIES, INC. 510(k) NO: [K063345](#)<sup>153</sup>(TRADITIONAL)  
ATTN: ALLISON MANNERS PHONE NO : 905 629 3822  
2585 SKYMARK AVENUE, STE. 306 SE DECISION MADE: 12-JAN-07  
MISSISSAUGA, ONTARIO, CANADA L4W 4S10(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: NUVASIVE ACP4 SYSTEM

NUVASIVE, INC. 510(k) NO: [K062590](#)<sup>154</sup>(SPECIAL)  
ATTN: LAETITIA COUSIN PHONE NO : 858-909-1868  
4545 TOWNE CENTRE CT. SE DECISION MADE: 18-JAN-07  
SAN DIEGO, CA 92121 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: MODIFICATION TO NUVASIVE NEUROVISION JJB SYSTEM

NUVASIVE, INC. 510(k) NO: [K062765](#)<sup>155</sup>(SPECIAL)  
ATTN: LAETITIA COUSIN PHONE NO : 858-909-1968  
4545 TOWNE CENTRE CT. SE DECISION MADE: 24-JAN-07  
SAN DIEGO, CA 92121 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: OSFERION

OLYMPUS AMERICA, INC. 510(k) NO: [K061499](#)<sup>156</sup>(TRADITIONAL)  
ATTN: LAURA STORMS-TYLER PHONE NO : 631-844-5688  
3500 CORPORATE PKWY. SE DECISION MADE: 26-JAN-07  
P.O. BOX 610 510(k) SUMMARY AVAILABLE FROM FDA  
CENTER VALLEY, PA 18034-0610

## DEVICE: OMNIGUIDE ZERO FLOW ZF-T WAVEGUIDE FIBER

OMNIGUIDE, INC. 510(k) NO: [K070071](#)<sup>157</sup>(TRADITIONAL)  
ATTN: DOUGLAS W WOODRUFF PHONE NO : 617-551-8404  
ONE KENDALL SQUARE, BLDG 100 SE DECISION MADE: 25-JAN-07  
3RD FLOOR 510(k) SUMMARY AVAILABLE FROM FDA  
CAMBRIDGE, MA 02139 THIRD PARTY REVIEW

## DEVICE: VUSION TS, PS, AND CS PARTIAL VERTEBRAL BODY REPLACEMENTS

ORTHO DEVELOPMENT CORP. 510(k) NO: [K062666](#)<sup>158</sup>(TRADITIONAL)  
ATTN: WILLIAM J GRIFFIN PHONE NO : 801-619-3470  
12187 SOUTH BUSINESS PARK DR. SE DECISION MADE: 25-JAN-07  
DRAPER, UT 84020 510(k) STATEMENT

## DEVICE: EUROPEAN STYLE TAPER,PRESS-FIT HIP STEM

ORTHO DEVELOPMENT CORP. 510(k) NO: [K062775](#)<sup>159</sup>(TRADITIONAL)  
ATTN: WILLIAM J GRIFFIN PHONE NO : 801-619-3470  
12187 SOUTH BUSINESS PARK DR. SE DECISION MADE: 16-JAN-07  
DRAPER, UT 84020 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: VITROS CHEMISTRY PRODUCTS BARB REAGENT; CALIBRATOR KIT 26; FS CA

ORTHO-CLINICAL DIAGNOSTICS 510(k) NO: [K062165](#)<sup>160</sup>(TRADITIONAL)  
ATTN: MARLENE HANNA PHONE NO : 585-453-4041  
100 INDIGO CREEK DR. SE DECISION MADE: 05-JAN-07  
ROCHESTER, NY 14626-5101 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: TS-BONE HIP TOOL

ORTHOPEDIC SCIENCES, INC 510(k) NO: [K063709](#)<sup>161</sup>(SPECIAL)  
ATTN: JAMES K BRANNON PHONE NO : 562-799-5550  
3020 OLD RANCH PARKWAY SE DECISION MADE: 04-JAN-07  
SUITE 325 510(k) SUMMARY AVAILABLE FROM FDA  
SEAL BEACH, CA 90740

## DEVICE: INTEGRITY LOW SPEED DENTAL AIR HANDPIECE AND ATTACHMENT, MODELS:

OSSEO SCIENTIFIC, LLC 510(k) NO: [K070155](#)<sup>162</sup>(TRADITIONAL)  
ATTN: MICHAEL FELDMAN PHONE NO : 201-490-5421  
3138 VEEDER AVE. SE DECISION MADE: 25-JAN-07  
TOMS RIVER, NJ 08753 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: EXPEDITIONARY DELPLOYABLE OXYGEN CONCENTRATION SYSTEM (EDOCS), M  
PACIFIC CONSOLIDATED INDUSTRIES, L510(k) NO: [K061414](#)<sup>163</sup>(TRADITIONAL)  
ATTN: GARY CLARK PHONE NO : 951-479-0872  
12201 MAGNOLIA AVE. SE DECISION MADE: 22-JAN-07  
RIVERSIDE, CA 92503 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PAJUNKS STIMULONG TSUI-METHOD SET  
PAJUNK GMBH MEDIZINTECHNOLOGIE 510(k) NO: [K062900](#)<sup>164</sup>(TRADITIONAL)  
ATTN: CHRISTIAN QUASS PHONE NO : 49 770 49291586  
KARL-HALL-STRASSE 01 SE DECISION MADE: 12-JAN-07  
GEISINGEN, BADEN-WURTTENBERG, GERM510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TROCASYS  
PAJUNK GMBH MEDIZINTECHNOLOGIE 510(k) NO: [K063528](#)<sup>165</sup>(TRADITIONAL)  
ATTN: CHRISTIAN QUASS PHONE NO : 49 770 48291  
KARL-HALL-STRASSE 01 SE DECISION MADE: 17-JAN-07  
GEISINGEN, BADEN-WURTTENBERG, GERM510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: FUZE MECHANICAL WHEELCHAIR, MODELS T20 AND T50  
PDG PRODUCT DESIGN GROUP, INC. 510(k) NO: [K063736](#)<sup>166</sup>(TRADITIONAL)  
ATTN: EDWARD A KROLL PHONE NO : 440-546-9810  
5905 FAWN LANE SE DECISION MADE: 17-JAN-07  
CLEVELAND, OH 44141 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: COSMELIGHT  
PENNTACK ENTERPRISES INC. 510(k) NO: [K061720](#)<sup>167</sup>(TRADITIONAL)  
ATTN: PABLO PENA PHONE NO : 305-835-0411  
3321 N.W. 79TH ST. SE DECISION MADE: 31-JAN-07  
MIAMI, FL 33147 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PREMIO  
PETERS SURGICAL 510(k) NO: [K060465](#)<sup>168</sup>(TRADITIONAL)  
ATTN: ANNIE LASSERRE PHONE NO : 33 148 106259  
42 RUE BENOIT FRACHON SE DECISION MADE: 17-JAN-07  
Z.I. LES VIGNES 510(k) SUMMARY AVAILABLE FROM FDA  
BOBIGNY, FRANCE 93013

DEVICE: HEARTSTART MRX, MODELS M3535A OR M3536A  
PHILIPS MEDICAL SYSTEMS 510(k) NO: [K063375](#)<sup>169</sup>(SPECIAL)  
ATTN: DENISE HALEY PHONE NO : 978-659-4358  
3000 MINUTEMAN RD. SE DECISION MADE: 11-JAN-07  
ANDOVER, MA 01810-1099 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ACHIEVA, INTERA AND PANORAMA 1.0T, RELEASE 2.5  
PHILIPS MEDICAL SYSTEMS 510(k) NO: [K063559](#)<sup>170</sup>(TRADITIONAL)  
ATTN: JOSEPH S ARNAUDO PHONE NO : 425-482-8958  
22100 BOTHELL EVERETT HWY SE DECISION MADE: 04-JAN-07  
BOTHELL, WA 98021-8431 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: PHILIPS XD-S DIRECT RADIOGRAPHY WORKSTATION/PACKAGE  
PHILIPS MEDICAL SYSTEMS NORTH AMER510(k) NO: [K063781](#)<sup>171</sup>(TRADITIONAL)  
ATTN: LYNN HARMER PHONE NO : 425-487-7312  
22100 BOTHELL EVERETT HIGHWAY SE DECISION MADE: 05-JAN-07  
BOTHELL, WA 98021-8431 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: PTS PANELS METABOLIC CHEMISTRY PANEL TEST STRIPS  
POLYMER TECHNOLOGY SYSTEMS, INC. 510(k) NO: [K070017](#)<sup>172</sup>(SPECIAL)  
ATTN: MARGO ENRIGHT PHONE NO : 317-870-5610  
7736 ZIONSVILLE RD. SE DECISION MADE: 31-JAN-07  
INDIANAPOLIS, IN 46268 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PORTLAND COBALT CHROME FEMORAL HEAD

PORTLAND ORTHOPAEDICS LIMITED 510(k) NO: [K063278](#)<sup>173</sup>(TRADITIONAL)  
ATTN: ELAINE DUNCAN PHONE NO : 715-549-6035  
P.O. BOX 560 SE DECISION MADE: 12-JAN-07  
STILLWATER, MN 55082 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: POWER EXTENDERS MODEL# PEC200, PES200,PES200S

POWER MEDICAL INTERVENTIONS, INC. 510(k) NO: [K063746](#)<sup>174</sup>(SPECIAL)  
ATTN: BARBARA WHITMAN PHONE NO : 267-775-8151  
2021 CABOT BLVD. SE DECISION MADE: 12-JAN-07  
LANGHORNE, PA 19047 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DERMATHERAPY, MODEL 22216

PRECISION FABRICS GROUP, INC. 510(k) NO: [K061242](#)<sup>175</sup>(TRADITIONAL)  
ATTN: PAMELA J WEAGRAFF PHONE NO : 508-528-1745  
18 BRIDIE LANE SE DECISION MADE: 25-JAN-07  
NORFOLK, MA 02056 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PRORHYTHM PROMAP COAXIAL MAPPING CATHETER, MODELS PRI-MAP-15, PR

PRORHYTHM 510(k) NO: [K061678](#)<sup>176</sup>(TRADITIONAL)  
ATTN: JOHN J TALARICO PHONE NO : 631-981-3907  
105 COMAC ST. SE DECISION MADE: 12-JAN-07  
RONKONKOMA, NY 11779 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: REPRIEVE ENDOVASCULAR TEMPERATURE THERAPY SYSTEM

RADIANT MEDICAL 510(k) NO: [K063405](#)<sup>177</sup>(SPECIAL)  
ATTN: SCOTT A WILSON PHONE NO : 650-298-0748  
250 CHESAPEAKE DR. SE DECISION MADE: 08-JAN-07  
REDWOOD CITY, CA 94063 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TOPACS

RADIOLOGICAL SPECIALISTS, INC. 510(k) NO: [K063294](#)<sup>178</sup>(TRADITIONAL)  
ATTN: FRANK MCMURRAY PHONE NO : 818-908-9000  
5920 NOBLE AVE. SE DECISION MADE: 24-JAN-07  
VAN NUYS, CA 91411 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TOSCA 500 TCPCO2, SPO2 AND PULSE RATE MONITORING SYSTEM

RADIOMETER BASEL AG 510(k) NO: [K063434](#)<sup>179</sup>(TRADITIONAL)  
ATTN: JEAN-PIERRE PALMA PHONE NO : 011 416 12788207  
AUSTRASSE 25 SE DECISION MADE: 22-JAN-07  
BASEL, SWITZERLAND 4051 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: COR ANALYZER 1, VERSION 1.4

RCADIA MEDICAL IMAGING LTD. 510(k) NO: [K063548](#)<sup>180</sup>(TRADITIONAL)  
ATTN: DAN LAOR PHONE NO : 972 4 8246632  
DERECH YAFO 157 SE DECISION MADE: 22-JAN-07  
HAIFA, ISRAEL 35251 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: FRAXEL II SR LASER SYSTEM

RELIANT TECHNOLOGIES, INC. 510(k) NO: [K062303](#)<sup>181</sup>(TRADITIONAL)  
ATTN: HEATHER TANNER PHONE NO : 650-641-5861  
464 ELLIS ST. SE DECISION MADE: 31-JAN-07  
MOUNTAIN VIEW, CA 94043 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: COBAS INTEGRA C 111

ROCHDIAG 510(k) NO: [K063744](#)<sup>182</sup>(SPECIAL)  
ATTN: CORINA HARPER PHONE NO : 317-521-3831  
9115 HAGUE RD. SE DECISION MADE: 17-JAN-07  
INDIANAPOLIS, IN 46250-0457 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: CERULOPLASMIN, MODEL 2055953

ROCHE DIAGNOSTICS CORP. 510(k) NO: [K062114](#)<sup>183</sup>(TRADITIONAL)  
ATTN: CORINA HARPER PHONE NO : 317-521-3831

9115 HAGUE RD. SE DECISION MADE: 31-JAN-07  
INDIANAPOLIS, IN 46250 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: COBAS INTEGRA CERULOPLASMIN

ROCHE DIAGNOSTICS CORP. 510(k) NO: [K062379](#)<sup>184</sup>(TRADITIONAL)  
ATTN: CORINA HARPER PHONE NO : 317-521-3831  
9115 HAGUE RD. SE DECISION MADE: 31-JAN-07  
INDIANAPOLIS, IN 46250 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: COAGUCHEK XS SYSTEM

ROCHE DIAGNOSTICS CORP. 510(k) NO: [K062925](#)<sup>185</sup>(TRADITIONAL)  
ATTN: THERESA BUSH PHONE NO : 317-521-3742  
9115 HAGUE RD. SE DECISION MADE: 29-JAN-07  
INDIANAPOLIS, IN 46256 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: COAGUCHEK XS PT CONTROLS

ROCHE DIAGNOSTICS CORP. 510(k) NO: [K063823](#)<sup>186</sup>(TRADITIONAL)  
ATTN: THERESA AMBROSE BUSH PHONE NO : 307-521-3723  
9115 HAGUE RD. SE DECISION MADE: 29-JAN-07  
INDIANAPOLIS, IN 46250 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: V2 TREATMENT SYSTEM (V2 CONSOLE, V2 ICE PROBE, V2 DEWARS) MODELS

SANARUS MEDICAL, INC. 510(k) NO: [K062896](#)<sup>187</sup>(TRADITIONAL)  
ATTN: ALAN MARQUARDT PHONE NO : 925-460-6080  
4696 WILLOW RD. SE DECISION MADE: 03-JAN-07  
PLEASANTON, CA 94588 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: ASTRA 300

SDI DIAGNOSTICS, INC. 510(k) NO: [K061571](#)<sup>188</sup>(TRADITIONAL)  
ATTN: COSIMO CARIOLO PHONE NO : 508-238-7033  
10 HAMPDEN DR. SE DECISION MADE: 31-JAN-07  
EASTON, MA 02375 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: ASTRAGUARD PULMONARY FUNCTION FILTER

SDI DIAGNOSTICS, INC. 510(k) NO: [K062913](#)<sup>189</sup>(TRADITIONAL)  
ATTN: COSIMO CARIOLO PHONE NO : 508-238-7033  
10 HAMPDEN DR. SE DECISION MADE: 26-JAN-07  
EASTON, MA 02375 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: QMS LAMOTRIGINE ASSAY (REAGENTS), CALIBRATORS &amp; CONTROLS

SERADYN INC. 510(k) NO: [K062966](#)<sup>190</sup>(TRADITIONAL)  
ATTN: JACK ROGERS PHONE NO : 317-610-3823  
7998 GEORGETOWN RD. SE DECISION MADE: 12-JAN-07  
SUITE 1000 510(k) SUMMARY AVAILABLE FROM FDA  
INDIANAPOLIS, IN 46268-5260

## DEVICE: POWDER FREE (YELLOW) VINYL PATIENT EXAMINATION

SHIJIAZHANG LIANHE SHUNDA PLASTIC 510(k) NO: [K070044](#)<sup>191</sup>(TRADITIONAL)  
ATTN: KATHY LIU PHONE NO : 909-591-7888  
3973 SCHAEFER AVE SE DECISION MADE: 29-JAN-07  
CHINO, CA 91710 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: SYNGO CIRCULATION SOFTWARE PACKAGE WITH EXTENDED FUNCTIONALITY

SIEMENS AG, MEDICAL SOLUTIONS 510(k) NO: [K063762](#)<sup>192</sup>(TRADITIONAL)  
ATTN: KRISTIN FROWEIN PHONE NO : 49 919 1189638  
SIEMENSSTRASSE 1 SE DECISION MADE: 05-JAN-07  
FORCHHEIM, GERMANY D 91301 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

## DEVICE: ACUSON P10 DIAGNOSTIC ULTRASOUND SYSTEM

SIEMENS MEDICAL SOLUTIONS USA, INC 510(k) NO: [K063761](#)<sup>193</sup>(TRADITIONAL)  
ATTN: MICHAELA MAHL PHONE NO : 650-694-5653  
1230 SHOREBIRD WAY SE DECISION MADE: 04-JAN-07  
MOUNTAIN VIEW, CA 94043 510(k) SUMMARY AVAILABLE FROM FDA

## THIRD PARTY REVIEW

DEVICE: SYNGO MI APPLICATIONS 2007A

SIEMENS MEDICAL SOLUTIONS USA, INC510(k) NO: **K063826**<sup>194</sup>(SPECIAL)  
ATTN: FRANK POKROP PHONE NO : 847-304-7516  
2501 NORTH BARRINGTON RD. SE DECISION MADE: 12-JAN-07  
HOFFMAN ESTATES, IL 60195-7372 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ACUSON ANTARES DIAGNOSTIC ULTRASOUND SYSTEM

SIEMENS MEDICAL SOLUTIONS USA, INC510(k) NO: **K063803**<sup>195</sup>(TRADITIONAL)  
ATTN: MICHAELA MAHL PHONE NO : 650-694-5653  
1230 SHOREBIRD WAY SE DECISION MADE: 05-JAN-07  
P O BOX 7393 510(k) SUMMARY AVAILABLE FROM FDA  
MOUNTAIN VIEW, CA 94039-7393 THIRD PARTY REVIEW

DEVICE: SMITH &amp; NEPHEW DUONICS POWER II SHAVER SYSTEM

SMITH & NEPHEW, INC. 510(k) NO: **K062849**<sup>196</sup>(TRADITIONAL)  
ATTN: KATHLEEN BURNS PHONE NO : 978-474-6301  
150 MINUTEMAN RD. SE DECISION MADE: 19-JAN-07  
ANDOVER, MA 01810 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: PORTEX HYPODERMIC NEEDLE- PRO EDGE SAFETY DEVICE, 18GX1, 401810,

SMITHS MEDICAL ASD, INC. 510(k) NO: **K063450**<sup>197</sup>(ABBREVIATED)  
ATTN: BRIAN FARIAS PHONE NO : 603-352-3812  
10 BOWMAN DR. SE DECISION MADE: 25-JAN-07  
KEENE, NH 03431 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: SOLARIS COMPATIBLE REUSABLE ADULT SPO2 FINGER SENSORS, MODELS S1

SOLARIS MEDICAL TECHNOLOGY, INC. 510(k) NO: **K061931**<sup>198</sup>(TRADITIONAL)  
ATTN: THOMAS KROENKE PHONE NO : 303-956-4232  
2355 EAST FLAMINGO ROAD SE DECISION MADE: 31-JAN-07  
SUITE 201 G 510(k) SUMMARY AVAILABLE FROM FDA  
LAS VEGAS, NV 89119

DEVICE: SOMNOSCREEN

SOMNOMEDICS GMBH & CO. KG 510(k) NO: **K060708**<sup>199</sup>(TRADITIONAL)  
ATTN: CHERITA JAMES PHONE NO : 202-546-1262  
719 A STREET NE SE DECISION MADE: 24-JAN-07  
WASHINGTON, DC 20002 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: D130 PH.I.S.I.O DIDEKO KIDS NEONATAL ARTERIAL FILTER WITH 40 MIC

SORIN GROUP ITALIA S.R.L 510(k) NO: **K063255**<sup>200</sup>(TRADITIONAL)  
ATTN: BARRY SALL PHONE NO : 781-434-4742  
200 WEST STREET SE DECISION MADE: 11-JAN-07  
WALTHAM, MA 02451 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: 15.5 FR DECATHLON GOLD, FUNNEL TIPS, COATED HEMODIALYSIS CATHETE

SPIRE BIOMEDICAL INC 510(k) NO: **K063431**<sup>201</sup>(TRADITIONAL)  
ATTN: SHEKHAR D NIMKAR PHONE NO : 781-275-6001  
ONE PATRIOTS PARK SE DECISION MADE: 29-JAN-07  
BEDFORD, MA 01730 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: STEAMPLUS STEAM INTEGRATOR

SPS MEDICAL SUPPLY CORP. 510(k) NO: **K063799**<sup>202</sup>(TRADITIONAL)  
ATTN: GARY J SOCOLA PHONE NO : 585-359-0130  
6789 WEST HENRIETTA RD. SE DECISION MADE: 05-JAN-07  
RUSH, NY 14543 510(k) SUMMARY AVAILABLE FROM FDA  
THIRD PARTY REVIEW

DEVICE: PROVEN KNEE SYSTEM HIGH FLEXION TIBIAL INSERT

STELKAST COMPANY 510(k) NO: **K063211**<sup>203</sup>(TRADITIONAL)  
ATTN: DAVID J STUMPO PHONE NO : 724-941-6368  
200 HIDDEN VALLEY RD. SE DECISION MADE: 18-JAN-07  
MCMURRAY, PA 15317 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: STRAUMANN PREFGEL

STRAUMANN USA 510(k) NO: [K063812](#)<sup>204</sup>(SPECIAL)  
ATTN: LISA M QUAGLIA PHONE NO : 978-747-2575  
60 MINUTETEMAN ROAD SE DECISION MADE: 12-JAN-07  
ANDOVER, MA 01810 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: SIMPLEX P BONE CEMENT

STRYKER ORTHOPAEDICS 510(k) NO: [K062553](#)<sup>205</sup>(TRADITIONAL)  
ATTN: TIFFANI D ROGERS PHONE NO : 201-831-5612  
325 CORPORATE DRIVE SE DECISION MADE: 08-JAN-07  
MAHWAH, NJ 07430 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: MODIFICATION TO HIPSTAR FEMORAL STEM

STRYKER ORTHOPAEDICS 510(k) NO: [K063822](#)<sup>206</sup>(SPECIAL)  
ATTN: TIFFANI ROGERS PHONE NO : 201-831-5612  
325 CORPORATE DRIVE SE DECISION MADE: 25-JAN-07  
MAHWAH, NJ 07430 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: POWDERED VINYL PATIENT EXAMINATION GLOVE

SUPER SAFE PLASTIC PRODUCTS CO., L510(k) NO: [K070035](#)<sup>207</sup>(TRADITIONAL)  
ATTN: KATHY LIU PHONE NO : 909-591-7888  
3973 SCHAEFER AVE SE DECISION MADE: 23-JAN-07  
CHINO, CA 91710 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: POWDERED VINYL PATIENT EXAMINATION GLOVES, WHITE

SUPER SAFE PLASTIC PRODUCTS CO., L510(k) NO: [K070040](#)<sup>208</sup>(TRADITIONAL)  
ATTN: KATHY LIU PHONE NO : 909-591-7888  
3973 SCHAEFER AVE SE DECISION MADE: 26-JAN-07  
CHINO, CA 91710 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: ENSEAL PTC TRIO

SURGRX, INC. 510(k) NO: [K070165](#)<sup>209</sup>(SPECIAL)  
ATTN: LINDA OLESON PHONE NO : 650-482-2400  
101 SAGINAW DR. SE DECISION MADE: 29-JAN-07  
REDWOOD CITY, CA 94063 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: TISSUE SITE MARKING SYSTEM

SUROS SURGICAL SYSTEMS, INC. 510(k) NO: [K062528](#)<sup>210</sup>(TRADITIONAL)  
ATTN: HEIDI STRUNK PHONE NO : 317-344-7500  
6100 TECHNOLOGY CENTER DR. SE DECISION MADE: 26-JAN-07  
INDIANAPOLIS, IN 46278 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: LINGLOCK

SYBRON DENTAL SPECIALTIES 510(k) NO: [K061042](#)<sup>211</sup>(TRADITIONAL)  
ATTN: COLLEEN BOSWELL PHONE NO : 949-255-8766  
100 BAYVIEW CIRCLE SE DECISION MADE: 19-JAN-07  
SUITE 6000 510(k) SUMMARY AVAILABLE FROM FDA  
NEWPORT BEACH, CA 92660-8915

## DEVICE: SYNTHES (USA) CONDYLAR HEAD ADD-ON SYSTEM

SYNTHES (USA) 510(k) NO: [K063181](#)<sup>212</sup>(TRADITIONAL)  
ATTN: DEBORAH L JACKSON PHONE NO : 610-719-6948  
1301 GOSHEN PKWY SE DECISION MADE: 05-JAN-07  
WEST CHESTER, PA 19380 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: SYNTHES ORACLE SPACER

SYNTHES SPINE CO.LP 510(k) NO: [K062933](#)<sup>213</sup>(TRADITIONAL)  
ATTN: BONNIE J SMITH PHONE NO : 610-719-5725  
1302 WRIGHTS LANE EAST SE DECISION MADE: 31-JAN-07  
WEST CHESTER, PA 19380 510(k) SUMMARY AVAILABLE FROM FDA

## DEVICE: CLEVER CHEK TD-3213/ CLEVER CHEK TD-3215/ DR. T TD-3216/ CLEVER

TAIDOC TECHNOLOGY CORPORATION 510(k) NO: [K062800](#)<sup>214</sup>(TRADITIONAL)





# 102  
BONITA SPRINGS, FL 34134

510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: POLYSORB\* SYNTHETIC ABSORBABLE SUTURE WITH MODIFIED PACKAGING  
TYCO HEALTHCARE GROUP  
ATTN: ROBERT ZOTT  
150 GLOVER AVE.  
NORWALK, CT 06856

510(k) NO: [K063536](#)<sup>225</sup>(TRADITIONAL)  
PHONE NO : 203-845-4515  
SE DECISION MADE: 29-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: U2 HIP STEM, TI PLASMA SPRAY  
UNITED ORTHOPEDIC CORP.  
ATTN: GENE HUANG  
57 PARK AVE. 2, SCIENCE PARK  
HSINCHU, CHINA (TAIWAN) 300

510(k) NO: [K062978](#)<sup>226</sup>(TRADITIONAL)  
PHONE NO : 886 3 5773351  
SE DECISION MADE: 16-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: EASYGLUCO, MODEL IGM-0002 G2  
US DIAGNOSTICS, INC.  
ATTN: EDWARD LETKO  
304 PARK AVENUE SOUTH  
SUITE 218  
NEW YORK, NY 10010-4301

510(k) NO: [K061431](#)<sup>227</sup>(TRADITIONAL)  
PHONE NO : 212-674-3636  
SE DECISION MADE: 12-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: INNERCHANGE MICRO-INTRODUCER CATHETER, MODELS 7900 THROUGH 7905  
VASCULAR SOLUTIONS, INC.  
ATTN: PATRICE STROMBERG  
6464 SYCAMORE COURT NORTH  
MINNEAPOLIS, MN 55369

510(k) NO: [K062627](#)<sup>228</sup>(TRADITIONAL)  
PHONE NO : 763-656-4300  
SE DECISION MADE: 05-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TWIN-PASS .023 DUAL ACCESS CATHETER, MODEL 5230  
VASCULAR SOLUTIONS, INC.  
ATTN: JULIE TAPPER  
6464 SYCAMORE COURT NORTH  
MINNEAPOLIS, MN 55369

510(k) NO: [K062877](#)<sup>229</sup>(TRADITIONAL)  
PHONE NO : 763-656-4228  
SE DECISION MADE: 18-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: AUTO-FILL SYRINGE KIT, MODEL 7600  
VASCULAR SOLUTIONS, INC.  
ATTN: PATRICE STROMBERG  
6464 SYCAMORE COURT NORTH  
MINNEAPOLIS, MN 55369

510(k) NO: [K063851](#)<sup>230</sup>(TRADITIONAL)  
PHONE NO : 763-656-4300  
SE DECISION MADE: 26-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: VERTIFLEX SPINAL SCREW SYSTEM  
VERTIFLEX (TM), INCORPORATED  
ATTN: STEVE REITZLER  
1954 KELLOGG AVENUE, SUITE 100  
CARLSBAD, CA 92008

510(k) NO: [K062670](#)<sup>231</sup>(TRADITIONAL)  
PHONE NO : 760-448-4800  
SE DECISION MADE: 12-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: EZ-MIO STERNAL  
VIDACARE CORPORATION  
ATTN: GRACE HOLLAND  
3722 AVE. SAUSALITO  
IRVINE, CA 92606

510(k) NO: [K063567](#)<sup>232</sup>(TRADITIONAL)  
PHONE NO : 949-262-0411  
SE DECISION MADE: 26-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: VISION BIOSYSTEMS PROGESTERONE RECEPTOR PGR CLONE 16  
VISION BIOSYSTEMS INC.  
ATTN: RONALD F LAGERQUIST  
1833 PORTOLA ROAD  
VENTURA, CA 93003

510(k) NO: [K062615](#)<sup>233</sup>(ABBREVIATED)  
PHONE NO : 805-499-6758  
SE DECISION MADE: 29-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: MERON PLUS  
VOCO GMBH  
ATTN: MICHAEL SUS  
ANTON-FLETTNER-STRASSE 1-3  
CUXHAVEN, GERMANY D-27472

510(k) NO: [K063554](#)<sup>234</sup>(ABBREVIATED)  
PHONE NO : 49 472 1719214  
SE DECISION MADE: 12-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: TWINKY STAR NF

VOCO GMBH 510(k) NO: [K063604](#)<sup>235</sup>(ABBREVIATED)  
ATTN: MANFRED THOMAS PLAUMANN PHONE NO : 49 472 17190  
ANTON-FLETTNER-STRASSE 1-3 SE DECISION MADE: 22-JAN-07  
CUXHAVEN, GERMANY D-27472 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: DEXTROSCOPE, MODEL MK10; DEXTROBEAM, MODEL MK3, MK4; RADIODEXTER

VOLUME INTERACTIONS PTE LTD 510(k) NO: [K063730](#)<sup>236</sup>(SPECIAL)  
ATTN: VALERIE FAN PHONE NO : 65 622 26962  
1 KIM SENG PROMENADE SE DECISION MADE: 31-JAN-07  
#12-01 GREAT WORLD CITY EAST 510(k) STATEMENT  
TOWER, SINGAPORE, SINGAPORE 237994

DEVICE: WAKO LBA DCP TEST SYSTEM, MODEL 993-05301; DCP CONTROL SET, MODE

WAKO CHEMICALS, USA, INC. 510(k) NO: [K062368](#)<sup>237</sup>(TRADITIONAL)  
ATTN: LORI CREASY PHONE NO : 804-714-1932  
1600 BELLWOOD ROAD SE DECISION MADE: 31-JAN-07  
RICHMOND, VA 23237 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LORENZ TITANIUM FRACTURE / RECONSTRUCTION DEVICES AND PRE-BENT P

WALTER LORENZ SURGICAL, INC. 510(k) NO: [K063052](#)<sup>238</sup>(TRADITIONAL)  
ATTN: KIM REED PHONE NO : 904-741-4400  
1520 TRADEPORT DR. SE DECISION MADE: 12-JAN-07  
JACKSONVILLE, FL 32218 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: LUNDERQUIST WIRE GUIDE; DC WIRE GUIDE

WILLIAM COOK EUROPE APS 510(k) NO: [K061670](#)<sup>239</sup>(SPECIAL)  
ATTN: TINA H ANDERSON PHONE NO : 45 56 868760  
SANDET 6, DK-4632 SE DECISION MADE: 19-JAN-07  
BJAEVERSKOV, DENMARK 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: FUSION QUATTRO EXTRACTION BALLOON XL

WILSON-COOK MEDICAL, INC. 510(k) NO: [K063677](#)<sup>240</sup>(SPECIAL)  
ATTN: SCOTTIE FARIOLE PHONE NO : 336-744-0157  
4900 BETHANIA STATION RD. SE DECISION MADE: 05-JAN-07  
WINSTON-SALEM, NC 27105 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: HILGER DUAL-STIM NERVE STIMULATOR

WR MEDICAL ELECTRONICS CO. 510(k) NO: [K063560](#)<sup>241</sup>(ABBREVIATED)  
ATTN: GARY SYRING PHONE NO : 608-877-2635  
800 LAVANGER LANE SE DECISION MADE: 05-JAN-07  
STOUGHTON, WI 53589 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: XODUS MEDICAL ANTI-FOG SOLUTION

XODUS MEDICAL, INC. 510(k) NO: [K063587](#)<sup>242</sup>(TRADITIONAL)  
ATTN: BRENDA NIEL PHONE NO : 724-337-5500  
702 PROMINENCE DR. SE DECISION MADE: 09-JAN-07  
NEW KENSINGTON, PA 15068 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: QUIKLOT SPORT AND QUIKLOT SPORT SILVER

Z-MEDICA CORPORATION 510(k) NO: [K070010](#)<sup>243</sup>(SPECIAL)  
ATTN: GIACOMO BASADONNA PHONE NO : 203-294-0000  
4 FAIRFIELD BLVD. SE DECISION MADE: 25-JAN-07  
WALLINGFORD, CT 06492 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: POWDER-FREE VINYL PATIENT EXAMINATION GLOVES

ZIBO HENGDE PLASTIC & RUBBER PRODU 510(k) NO: [K070006](#)<sup>244</sup>(TRADITIONAL)  
ATTN: CHU XIAOAN PHONE NO : 86 10 82387441  
NO. 209 BEI SI HUAN ZHONG ROAD SE DECISION MADE: 19-JAN-07  
BEIJING, CHINA 10083 510(k) SUMMARY AVAILABLE FROM FDA

DEVICE: ZIMMER M/L TAPER HIP PROSTHESIS WITH MODULAR NECK TECHNOLOGY

ZIMMER, INC. 510(k) NO: [K063251](#)<sup>245</sup>(TRADITIONAL)

ATTN: DALENE T BINKLEY  
P.O. BOX 708  
WARSAW, IN 46581-0708

PHONE NO : 574-372-4907  
SE DECISION MADE: 24-JAN-07  
510(k) SUMMARY AVAILABLE FROM FDA

TOTAL 510(k)s THIS PERIOD	245
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