510(K) Summary

JUN - 5 2012

Contact Information

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Trade Name

Proprietary: CyberWand® Dual Action Ultrasonic Lithotripsy System
Common: Lithotriptor, Ultrasonic Intracorporeal

Classification

Product Code FFK, Class II, 21 CFR 876.4880 - Electrohydraulic lithotripter

Predicate Device

The CyberWand Dual Action Ultrasonic Lithotripsy System described in this Abbreviated 510(k) submission is, in our opinion, substantially equivalent with the predicate device, CyberWand Dual Probe Lithotripter (K052135).

Product Description

The CyberWand Dual Action Ultrasonic Lithotripsy System includes a Generator, Transducer (2), Footswitch, Power Cord, Wrench, and Cleaning Stylet. The disposable probe set is sold separately either sterile or non-sterile.

The Cybersonics CyberWand Dual Probe Ultrasonic Lithotripsy System is an electromechanical device capable of fragmenting and aspirating calculi. The hand piece consists of an ultrasonic transducer containing the piezoelectric elements, which are driven by a generator operating at 20400 – 22200 Hz. The resulting longitudinal waves are propagated along the ultrasonic dual probe to the target stone. The ultrasonic transducer probes are hollow, permitting simultaneous suction.

Indications for Use Statement

The CyberWand Dual Action Ultrasonic Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Basis for Substantial Equivalence

The Cybersonics CyberWand Dual Action Ultrasonic Lithotripsy System is substantially equivalent to the:

- CyberWand Dual Probe Lithotripter (K052135)
- CyberWand Hollow Semi-Flexible Ureteral Probe Lithotripter (K102169)

which were previously cleared for the fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder.

The CyberWand Dual Action Lithotripsy System has the following similarities to the above-referenced devices:

- Same indications for use
- Same ultrasonic technology
- Same operating principle
- Same basic configuration
- Same materials

Performance Data

The safety and effectiveness of the CyberWand Dual Action Ultrasonic Lithotripsy System is determined primarily by confirming that its design and performances conform to the established national and international standards and protocols applicable to lithotripters. The CyberWand Dual Action Ultrasonic Lithotripsy System complies with the requirements of each the standards and protocols discussed below.

Performance Considerations

IEC 61847:1998 – Ultrasonics, Surgical Systems – Measurement and Declaration of the Basic Output Characteristics. This international standard defines the parameters which characterize the output and performance of open and closed site ultrasonic surgical systems, and indicates which parameters should be declared. Cybersonics prepared an evaluation report which provides a declaration of output characteristics.

Verification and Validation studies for the Advanced Transducer were performed and documented in a formal report which included results for pre-sterilization and post-sterilization performance tests (Drill Rate Study, Laser Vibrometer Study, Surface Temperature Profile Study, Interface and Compatibility Study, Steam Sterilization and Endurance Durability Study).

Electrical Safety Considerations

The CyberWand Dual Action Ultrasonic Lithotripsy System is classified as Class I equipment with a Type BF applied part that complies with IEC 60601-1:2005 3rd Edition.

The purpose of the EMC Directive is to ensure the customer that all standards for manufacturing and operating the electronics of the device safely have been adhered to and followed. The EMC Directive also stipulates that the device will not emit radiation at levels that will interfere with other devices located nearby. Additionally, the EMC Directive will not transmit electro-magnetic surges back into the power grid at frequencies and amplitudes that are above the values listed in the standard.

The evaluation of the CyberWand Dual Action Ultrasonic Lithotripsy System illustrates that the unit meets the emission requirements of the EN 60601-1-2:2007 "Medical Electric Equipment – Part 1, Section 1.2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests" and with the requirements of IECES-003, Issue 4:2004, FCC Part 15, Subpart B and European Standard EN55011:2007 "Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Equipment" including Amendment A1:2010.

The evaluation of the CyberWand Dual Action Ultrasonic Lithotripsy System illustrates that the unit meets the immunity requirements of EN60601-1-2:2007 "Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests".

The evaluation of the CyberWand Dual Action Ultrasonic Lithotripsy System illustrates that the unit meets the requirements of EN61000-3-2:2006: "Electromagnetic Compatibility – Part 3-2: Limits for Harmonic Current Emissions (Equipment Input Current $\leq$ 16 Amps Per Phase)" including Amendments A1:2009 and A2:2009, and with EN61000-3-3:2008: "Electromagnetic Compatibility - Part 3-3: Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems for Equipment with Rated Current $\leq$ 16 Amps Per Phase and not Subject to Conditional Connection".

Software Validation Considerations

Software validation for the cycle operation has been performed according to the FDA's Moderate Level of Concern recommendations provided in the document "*Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (5/29/98).*"

Sterilization Validation Considerations

Steam Sterilization

Prevacuum steam sterilization technique has been qualified against the ISO 17665-:2006 "*Sterilization of Healthcare Products – Moist-Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices*" standard for the Advanced Transducer (USLTA). The results of the biological indicators and inoculated device indicated no spore survivors for three consecutive half cycles. The Cybersonics Advanced Transducer was judged to be effectively sterilized at 132C for a 2 minute Prevac half cycle and zero minute dry time. The cycle conditions are considered adequate to achieve an SAL minimum of 10^{-6} at twice the stated exposure time. The thermocouples passed the verification calibration. All positive and negative controls were satisfactory. A dry time of fifteen (15) minutes was successfully validated for the four (4) minute Prevac cycle at 132C for 4 minutes sterilize for the double wrapped transducer.

A steam sterilization study with the CyberWand probes was conducted to determine if exposure of the double wrapped probes would produce the required 10^{-6} sterility assurance level using the overkill method as defined in the AAMI-TIR:2004 *"Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers"*. The CyberWand probes, doubled wrapped, was judged to be effectively sterilized at 132C for a 2 minute Prevac half cycle and zero minute dry time.

Ethylene Oxide Sterilization

The Advanced Transducer was also validated in a 100% ethylene oxide sterilization cycle at 55C for 50 minutes sterilize with twelve (12) hour aeration against the ISO 10993-7:2008 "*Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*" standard. The study demonstrated that ethylene oxide (ETO), and its common degradants ethylene chlorohydrin (ECH) and ethylene glycol (EG), are within the allowable limits. The Advanced Transducer also demonstrated a sterility assurance level (SAL) of 10^{-6} using the biological indicator (*Bacillus atrophaeus* ATCC #9372) overkill method.

A study was conducted to validate the sterilization process for the CyberWand Sterile Probe Sets to confirm that the sterility assurance level (SAL) of 10^{-6} is obtained. This requalification was performed by Ethox and done in accordance with ANSI/AAMI/ISO 11135-1:2007 *Sterilization of healthcare products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of Sterilization Process for Medical Devices.* This study also included

bioburden testing and EO residual testing to verify the previously validated EO aeration hold time.

Conclusion

Cybersonics through its distributor conducts training of the sales representatives and users about the appropriate and proper use of the CyberWand Dual Action Ultrasonic Lithotripsy System. Cybersonics further provides information to the user that is intended to ensure safe and effective use of lithotripsy procedures in its Instructions for Use Manual and other labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lori Colvin
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ERIE PA 16510

JUN - 5 2012

Re: K120303
Trade/Device Name: CyberWand Dual Action Ultrasonic Lithotripsy System
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: May 25, 2012
Received: May 30, 2012

Dear Ms. Colvin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Document Control Number:

K120303

Device Name:

CyberWand Dual Action Ultrasonic Lithotripsy System

Indications for Use:

The CyberWand Dual Action Ultrasonic Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (21 CFR 801 Subpart D) or Over-The-Counter Use (21 CFR 801 Subpart C)

05 JUNE 2012

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120303