Contact Information

Lori A. Colvin, C.Q.A.
Director, Regulatory Affairs
Cybersonics, Inc.
5325 Kuhl Road
Erie, Pennsylvania 16510
Phone: 814-898-4734
Fax: 814-898-4737

Trade Name

Proprietary: CyberWand® Sterile Probe Set
Common: Lithotriptor, Ultrasonic Intracorporeal

Classification

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

Predicate Device

The CyberWand Sterile Probe Set described in this Special 510(k) submission is, in our opinion, substantially equivalent with the predicate devices, CyberWand Dual Action Ultrasonic Lithotripsy System (K120303) and CyberWand Probe Lithotripter with Sterile Probes (K072422).

Product Description

The CyberWand Dual Action Ultrasonic Lithotripsy System includes a Generator, Transducer, Footswitch, Power Cord, Wrench, and Cleaning Stylet. The CyberWand Sterile Probe Set is sold 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 Sterile Probe Set is designed to be used only with the CyberWand Dual Action Ultrasonic Lithotripsy System for the fragmentation of urinary tract calculi in the kidneys, ureter, and bladder.

Basis for Substantial Equivalence

The CyberWand Sterile Probe Set is substantially equivalent to the:

- CyberWand Dual Probe Lithotripter with Sterile Probes (K072422)
- CyberWand Dual Action Ultrasonic Lithotripsy System (K120303)

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

The CyberWand Sterile Probe Set 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

To verify that CyberWand Sterile Probe Set met the validation requirements to support the five year shelf life claim, representative samples of the device underwent package integrity testing in accordance with Cybersonics design change control process and risk management activities.

Package Integrity Validation

Expiration dating is supported based upon acceptable test results (2ACMI-07P1-O/2013-GMP-028) obtained from the following series of package integrity tests.

- Accelerated Aging of Packaging
- Real Time Aging of Packaging
- Simulated Ship Test & Inspection
- Dye Penetration Testing for Single Barrier Packages
- Burst Package Testing for Packages
- Peel Strength Test for Package Seals

Testing was conducted on non-aged, one (1) and three (3) year accelerated, and one (1) and five (5) year real time aged tyvek/film pouches used for the CyberWand Sterile Probe Set.

Based on the results, it has been determined that a five (5) year expiration date may be applied to the CyberWand Sterile Probe Set.

Conclusion

Cybersonics through its distributor conducts training of the sales representatives and users about the appropriate and proper use of the CyberWand Sterile Probe Set with 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 Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Cybersonics, Inc.
Lori a. Colvin, C.Q.A.
Director of Regulatory Affairs
5325 Kuhl Road
Erie, PA 16510

Re: K132795
Trade/Device Name: CyberWand Sterile Probe Set
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: October 29, 2013
Received: October 30, 2013

Dear Lori A. 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,

Herbert P. Lerner -S

for

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: K132795

Device Name:

CyberWand Sterile Probe Set

Indications for Use:

The CyberWand Sterile Probe Set is designed to be used only with the CyberWand Dual Action Ultrasonic Lithotripsy System for the fragmentation of urinary tract calculi in the kidneys, ureter, and bladder.

(Please do not write below this line – continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation

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

Herbert P. Lerner -S
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