K102169

AUG 30 2010

6. 510(K) SUMMARY

Submitter:	Cybersonics, Inc. 5325 Kuhl Road Erie, PA 16510 Phone: (814) 898-4734 Fax: (814)898-4737 Contact: Jeff Vaitekunas
Date Prepared:	July 30, 2010
Trade Name:	CyberWand® Lithotripter
Classification:	Class II, 21 CFR 876.4880, FFK Electrohydraulic lithotripter
Predicate Device(s):	The CyberWand Hollow Semi-Flexible Ureteral probe is equivalent to the Cyberwand Dual Probe Set (K052135).
Device Description:	The CyberWand Dual Ultrasonic Lithotripsy System is an electromechanical device used to fragment and aspirate calculi. The system consists of the generator unit, transducer handpiece, footswitch, probe sets and cleaning stylets. The Semi-Flexible Probe is constructed entirely of stainless steel and is packaged with a stainless steel cleaning stylet. The probe has a working length of 58.5 cm and an outer diameter of 1.65 mm; it is is intended to be used primarily with semi-rigid or ridged scopes (cystoscopes, nephroscopes and ureteroscopes) which have a working channel between 5 and 7 French in diameter. The probe is for provided non-sterile and is for single-patient use.
Intended Use:	The CyberWand Hollow Semi-Flexible Ureteral probes are designed to be used only with the CyberWand Dual Ultrasonic Lithotripsy System for the fragmentation of urinary tract calculi in the kidneys, ureter, and bladder.
Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative samples of the device underwent durability and stone breakage testing in accordance with Cybersonics Design Control processes and the risk assessment.
Conclusion:	Cybersonics considers the modified probes to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Jeff Vaitekunas
Vice-President Regulatory
Cybersonics, Inc.
5325 Kuhl Road
ERIE PA 16510

AUG 30 2010

Re: K102169
Trade/Device Name: Cybersonics CyberWand® Hollow Semi-Flexible Ureteral Probe
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: July 30, 2010
Received: August 2, 2010

Dear Mr. Vaitekunas:

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.

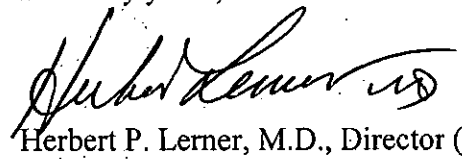
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102169

Device Name: Cybersonics CyberWand® Hollow Semi-Flexible Ureteral Probe

Indications for Use:

The CyberWand Hollow Semi-Flexible Ureteral probe is designed to be used only with the CyberWand System for the fragmentation of urinary tract calculi in the kidneys, ureter, and bladder.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K102169