DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 21, 2017

Cybersonics, Inc.
Samradni Patil
Regulatory Affairs Manager
Knowledge Park, 5340 Fryling Road, Suite 101
Erie, PA 16510

Re: K171024
Trade/Device Name: ShockPulse-SE Lithotripsy System
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: II
Product Code: FEO
Dated: July 24, 2017
Received: July 25, 2017

Dear Samradni Patil:

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 contact the Division of Industry and Consumer Education (DICE) 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171024

Device Name

ShockPulse-SE Lithotripsy System

Indications for Use *(Describe)*

ShockPulse-SE Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness
Cybersonics Inc.
ShockPulse-SE Lithotripsy System

General Information

Manufacturer:	Cybersonics, Inc. Knowledge Park 5340 Fryling Road, Suite 101 Erie, Pennsylvania 16510 USA Phone: 814 898 4734 Fax: 814 898 4737
Establishment Registration Number:	3004216443
Contact Person:	Samradni Patil Manager, Regulatory Affairs
Date Prepared:	April 3, 2017

Device Information

Classification Name:	Device Classification Name: Electrohydraulic lithotriptor, Regulation / CFR Citation Number: 21 CFR 876.4480 Product Code: FEO Class: II
Trade Name:	ShockPulse-SE Lithotripsy System
Generic/Common Name:	Lithotripter, Ultrasonic Intracorporeal

Predicate Devices

Predicate Device	ShockPulse-SE Lithotripsy System (K142428)

Device Description

The ShockPulse-SE Lithotripsy System is an electromechanical device capable of fragmenting calculi and aspirating stone debris. The ShockPulse-SE Lithotripsy System consists of generator, probes, transducer, cleaning stylet, wrench, power cord and nosecone. Footswitch is optional.

Intended Use/Indication for Use

ShockPulse-SE Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Comparison of Technological Characteristics with the Predicate Devices

	Predicate Device	**Proposed Device**
Device Name	ShockPulse-SE Lithotripsy System	ShockPulse-SE Lithotripsy System
510(k) Number(s)	K142428	To be Assigned
Product Code	FEO	FEO
Intended Use/Indication for Use	ShockPulse-SE Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.	ShockPulse-SE Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.
Principle of operation	Ultrasonic technology that uses a transducer to convert electrical energy to ultrasonic frequency vibrations that travel down the probe and break up stones.	Ultrasonic technology that uses a transducer to convert electrical energy to ultrasonic frequency vibrations that travel down the probe and break up stones.
Applied Part Type	Type BF	Type BF
Ultrasonic Maximum Output to Transducer	100 Watts	100 Watts
Ultrasonic Frequency	19,500 Hz – 21,500 Hz	19,500 Hz – 21,500 Hz
Sterilization Method for disposable probes	Ethylene Oxide	Ethylene Oxide
Sterilization Method of reusable probes	Prevac Cycle (USA), Prevac Flash Cycle	Prevac Cycle (USA), Prevac Flash Cycle
Material for 3.76mm and 3.40mm probe tube	304 Stainless Steel	304 Stainless Steel coated with diamond like carbon
Material for 1.83mm, 1.50mm and 0.97mm probe tube	304 Stainless Steel	304 Stainless Steel

Device modifications described in the submission do not affect the intended use or the technological characteristics of the ShockPulse-SE Lithotripsy System.

Performance Data

Testing has confirmed that the proposed ShockPulse-SE Lithotripsy System functions as intended and is substantially equivalent to the predicate device.

Performance Testing Performed	
Electrical Safety	Pass
EMC/EMI	Pass
Biocompatibility	Pass
Bioburden	Pass
EO Residuals	Pass
Mass removal rate	Pass
Drill rate	Pass
Displacement	Pass
Frequency	Pass

Conclusions

The proposed ShockPulse-SE Lithotripsy System is substantially equivalent to the predicate device. The modifications in the device do not affect the intended use or the technological characteristics for the system and do not raise different questions of safety or effectiveness.