K101847

Section 5: 510(k) Summary

Date Prepared	October 8, 2010
New Device Name	Urgent® PC Neuromodulation System
Predicate Device	Urgent® PC Neuromodulation System (K071822)
Contact	Uroplasty, Inc. 5420 Feltl Road Minnetonka, MN 55343 USA Tel: 952.426.6140; Fax: 952.426.6199

OCT 2 1 2010

Intended Use

The Urgent PC Neuromodulation System is intended to treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Device Description

The Urgent® PC Neuromodulation System is a minimally invasive neuromodulation system designed to deliver retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve. The method of treatment is referred to as Percutaneous Tibial Nerve Stimulation (PTNS).

The Urgent PC Neuromodulation System is a combination of the Urgent PC Stimulator and the Urgent PC Stimulation Lead Set. The Urgent PC Stimulator is a battery-operated external pulse generator and is designed, constructed, and manufactured for multiple use, only in conjunction with the Urgent PC Stimulation Lead Set. The Urgent PC Stimulation Lead Set transfers the electrical current from the Urgent PC Stimulator to the tibial nerve via the Needle Electrode. The entire Stimulation Lead Set is intended for single use only and is not to be reused.

Indications Statement

The primary difference between the new and predicate devices is the wording of indications statement. The new device indications statement incorporates the overactive bladder terminology listed in the intended use. This difference in indication statement represents an update in wording rather than a change in the device patient population.

Technological Characteristics

The new and predicate devices are technologically the same; they are percutaneous tibial nerve stimulator devices with lead sets intended to deliver retrograde access to the sacral nerve for the overactive bladder symptoms of urinary urgency, urinary frequency, and urge incontinence. Both devices have the same intended use and principles of action. Only the wording of the indications statement differs between this device and the predicate.

Performance

The Urgent PC Neuromodulation System and Stimulation Lead Set allows for the successful performance of the product's intended use.

Conclusion

The subject device of the 510(k) submission is substantially equivalent to the previously cleared Urgent PC Neuromodulation System by Uroplasty, Inc. (K071822).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Mr. Michael Morrell, RAC
Director of Regulatory Affairs and Quality Assurance
Uroplasty, Inc.
5420 Feltl Road
MINNETONKA MN 55343

OCT 21 2010

Re: K101847
Trade/Device Name: Urgent® PC Neuromodulation System
Regulation Number: 21 CFR §876.5310
Regulation Name: Non-implanted, peripheral electrical continence device
Regulatory Class: II
Product Code: NAM
Dated: October 8, 2010
Received: October 14, 2010

Dear Mr. Morrell:

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.

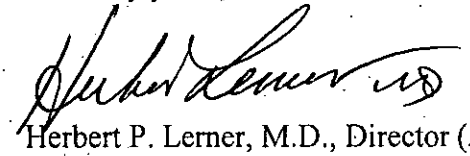
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K101847

Section 4: Indications for Use Statement

510(k) Number (if known): K101847

OCT 2 1 2010

Device Name: Urgent® PC Neuromodulation System

Indications for Use: The Urgent PC Neuromodulation System is intended to treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101847