Section 5: 510(k) Summary

AUG 2 0 2007

Date Prepared	July 2, 2007
New Device Name	Urgent® PC Neuromodulation System
Predicate Device	Urgent® PC Neuromodulation System (K061333)
Contact	Uroplasty, Inc. 5420 Feltl Road Minnetonka, MN 55343 USA Tel: 952.426.6140; Fax: 952.426.6199

Intended Use

The Urgent PC Neuromodulation System is intended to treat patients suffering from 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 Urgent PC Neuromodulation System is intended to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence by delivering retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve.

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 Instructions for Use 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. (K061333).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 2 0 2007

Ms. Lisa Gallatin
Regulatory Affairs Project Manager
Uroplasty, Inc.
5420 Feltl Road
MINNETONKA MN 55343-7982

Re: K071822
Trade/Device Name: Urgent® PC Neuromodulation System
Regulation Number: 21 CFR §876.5310
Regulation Name: Nonimplanted, peripheral electrical continence device
Regulatory Class: II
Product Code: NAM
Dated: July 2, 2007
Received: July 3, 2007

Dear Ms. Gallatin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K071822

Device Name: Urgent® PC Neuromodulation System

Indications for Use: The Urgent PC Neuromodulation System is intended to treat patients suffering from 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)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071822