K061333

Section 10: 510(k) Summary

JUL - 3 2006

Date Prepared	May 11, 2006
New Device Name	Urgent® PC Neuromodulation System
Predicate Device	Urgent® PC Neuromodulation System (K052025)
Contact	Uroplasty, Inc. 2718 Summer Street NE Minneapolis, MN 55413-2820 Telephone: (612) 378-9399, Facsimile: (612) 378-2027

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 similar intended uses and principles of action. In the few instances where the devices differ, no concerns about safety or effectiveness are raised.

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 this special 510(k) submission is substantially equivalent to the previously cleared Urgent PC Neuromodulation System by Uroplasty, Inc. (K052025).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Lisa Gallatin, R.A.C.
Regulatory Affairs Associate
Uroplasty, Inc.
2718 Summer Street, N.E.
MINNEAPOLIS MN 55413-2820

Re: K061333
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: June 14, 2006
Received: June 15, 2006

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 (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); 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.

In addition, we have determined that your device kit contains a 70% isopropyl alcohol prep pad, which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061333

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 (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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, Abdominal, and Radiological Devices
510(k) Number K061333