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ADVANCED URO-SOLUTIONS

510k Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE:	August 15, 2013
APPLICANT:	Advanced Uro-Solutions, Inc. Brent Laing, MD 2521 Beechwood Drive Elizabethton, TN 37643 423-612-0654 (phone) blaing@fmgmd.com (email)
OFFICIAL CORRESPONDENT FOR THIS SUBMISSION:	Penny Northcutt, RAC, FRAPS, CQA Regulatory Consultant for Advanced Uro-Solutions REGSolutions, LLC 678-428-6978 (phone) 678-513-0937 (fax) pennynorthcutt@theregsolutions.com (email)
TRADE NAME:	NURO Neuromodulation System
CLASSIFICATION NAME:	Stimulator, Peripheral Nerve, Non-Implanted, for Pelvic Floor Dysfunction
DEVICE CLASSIFICATION AND PRODUCT CODE:	Class II, per 876.5310 Product Code: NAM
PREDICATE DEVICE NAME:	Urgent PC, K101847

SUBSTANTIAL EQUIVALENCE:
The NURO Neuromodulation System is substantially equivalent to the legally marketed Urgent PC Neuromodulation System (K101847). Both the NURO Neuromodulation System and the Urgent PC System (predicate) are minimally invasive neuromodulation systems designed to deliver retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve.

The NURO Neuromodulation System contains an internal rechargeable lithium battery, and functions by using purchased therapy credits which are downloaded to the device via USB connection. The Urgent PC contains a 9V alkaline battery. These differences do not affect

the safety and efficacy of the NURO Neuromodulation System as compared to the predicate Urgent PC.

DESCRIPTION OF THE DEVICE:
The NURO Neuromodulation System is designed to deliver retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve. This method of treatment is referred to as Percutaneous Tibial Nerve Stimulation (PTNS).

The NURO Neuromodulation System is a combination of the Stimulator with permanently attached single insulated lead wire, and number of single-use accessories which are sold separately, including: the acupuncture needle (provided in a single-use sterile package), needle holder, and electrode pad. The Stimulator is a small and portable pulse generator, and should only be used in conjunction with the lead wire and the single-use items listed above. The system also includes a micro USB-to-USB cable, and a USB wall charger.

The Stimulator device provides treatment functions by purchasing therapy credits from a commercial website. Therapy credits are downloaded to the device through the micro-USB connection to a computer with a USB port and internet access. The Stimulator stores a record of the therapy credits purchased and available. Each therapy cycle uses a single credit. A therapy credit is required to be available on the Stimulator device in order to begin a patient treatment session. These therapy credits may be purchased with 99 as the maximum purchase. The Stimulator does not store or transfer via the USB cable any patient data. The credit transfer function is strictly a financial transaction. No patient data is stored or transferred by the Stimulator. There is no impact on safety or efficacy with purchase of therapy credits.

INTENDED USE/INDICATIONS FOR USE:
The NURO Neuromodulation System (Stimulator model NURO 100) is intended to treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

TECNOLOGICAL CHARACTERISTICS:
The NURO Neuromodulation System has substantially equivalent technological characteristics when compared to the predicate device. It has substantially equivalent indications for use, device construction, and principles of operation. Testing has demonstrated that the NURO Neuromodulation System performs effectively as intended and is safe as provided by the electrical testing. The descriptive and technological characteristics are functionally equivalent to the proposed predicate neuromodulation system. Any minor differences do not affect safety or effectiveness of the NURO Neuromodulation System.

The NURO Neuromodulation System and the predicate Urgent PC (K101847) devices are Class II devices regulated under CFR 876.5310, product code NAM.

The intended use of both devices is to treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence and both utilize percutaneous tibial nerve stimulation (PTNS) as the clinical mechanism to achieve patient continence. Both devices utilize the same clinical treatment protocol of 30 minutes using the same electrical waveform output. The two devices have consistent output

patterns, which is of ultimate importance in establishing the substantial equivalence relationship. The adjustable current ranges from a minimum setting of 0 mA to a maximum setting of 19mA for both Stimulators. The square waveforms delivered by both devices have fixed pulse widths of 200 microseconds and frequencies of 20Hz.

Both devices consist of a battery-powered electrical pulse generator (Stimulator) intended for multiple uses and supplied non-sterile. The NURO Stimulator runs on a lithium battery and the Urgent PC is powered by a 9V battery. Both devices are supplied with accessories, a surface electrode pad, and a sterile acupuncture needle, a needle holder (called Needle Electrode clip by Urgent PC), and an alcohol pad, obtained from original equipment manufacturers.

Both devices are controlled by software. Software on the NURO device was verified and validated to ensure compliance with the desired treatment protocol used by the predicate device for therapy to treat urinary urgency, urinary frequency, and urge incontinence. The treatment is dictated by the following characteristics: square output waveform, pulse width, pulse period, current output (minimum and maximum). With respect to these four characteristics, the NURO Neuromodulation System and the Urgent PC are substantially equivalent.

Differences in the two devices are mainly in the lead wire. The NURO device lead wire is permanently attached to the NRUO Stimulator and functions when therapy credits are uploaded to the device via connection to a commercial website. When the therapy credits are depleted, the device no longer provides treatment. Wherein the Urgent PC lead wire is for single use only and provides one treatment session with each lead wire containing a self-kill fuse which burns out after each use. Urgent PC lead wire is not permanently attached but mates with the Stimulator to provide a connection between the Stimulator and the needle electrode. The NURO lead wire is permanently attached to the NURO Stimulator. Neither lead wire has biocontact with the patient. Both designs work effectively; therefore, there is no impact on safety or effectiveness from this design difference.

Both the NURO Stimulator and the Urgent PC connect the current lead wire to the acupuncture needle (Needle Electrode) in the ankle utilizing a plastic needle holder (Needle Electrode clip). The main purpose of the needle holder is to complete the current path from the Stimulator to the inserted acupuncture needle (Needle Electrode).

The differences discussed here do not alter the fundamental scientific technology established from the predicate device; nor do they introduce any safety or effectiveness concerns about the NURO Neuromodulation System.

NONCLINICAL PERFORMANCE TESTING:
A series of performance tests was conducted in support of the design verification of the NURO Neuromodulation System.

Summary of Performance Testing Conducted on NURO Neuromodulation System	
Electrical Testing	IEC 60601-1:2005 Medical electrical equipment—Part 1-1: General requirements for basic safety and essential performance

Summary of Performance Testing Conducted on NURO Neuromodulation System	
	IEC 60601-1-2:2007 Medical electrical equipment—Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
	IEC 60601-2-10:2012 Medical electrical equipment—Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
Cleaning Validation	Cleaning Validation of NURO Stimulator

CONCLUSION:
Based on the verification performance, it can be concluded that the NURO Neuromodulation System is equivalent to the Urgent PC Neuromodulation System (K101847) with respect to intended use, principles of operation, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 5, 2013

Advanced Uro-Solutions
% Penny Northcutt
Regulatory Consultant
REGSolutions, LLC
717 Lakeglen Drive
Suwanee, GA 30024

Re: K132561
Trade/Device Name: NURO Neuromodulation System
Regulation Number: 21 CFR 876.5310
Regulation Name: Nonimplanted, Peripheral Electrical Continence Device
Regulatory Class: Class II
Product Code: NAM
Dated: October 1, 2013
Received: October 2, 2013

Dear Penny Northcutt:

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 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. 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,

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

2. INDICATIONS FOR USE

510(k) Number (if known): K132561

Device Name: **NURO Neuromodulation System**

Indications for Use:

The NURO Neuromodulation System (Stimulator model NURO 100) 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 _____

(Part 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)

Benjamin R. Fisher -S
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