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Traditional 510k –Signal gear Signal Gear Urethral Catheter Electrode

DEC 13 2012

5. 510(k) Summary
In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Applicant Information
Christine Vergely
Neurovision Medical Products Inc.
2225 Sperry Ave., Suite 1000
Ventura, CA 93003
Telephone Number: 866-815-6999
Fax: 413-410-4579
Email Address: christie@neurovisionmedical.com

Device Identification
Trade or Proprietary Name: Signal Gear Urethral Catheter Electrode
Device classification: 21 CFR 876.1620, Urodynamics Measurement System
Device class: Class II
Product code: FAP

Predicate Devices
The Signal Gear Urethral Catheter Electrode is substantially equivalent to the following predicate device previously distributed commercially in the U. S.:

- K874758 Dantec Electronic, Inc. St. Mark's Pudendal Electrode

Device Description
The Signal Gear Urethral Catheter Electrode is a single patient use, disposable sterile device. It consists of an adhesive, highly flexible, polyurethane film substrate that wraps around the urethral (Foley) catheter. The conductive portion of the electrode is printed onto the polyurethane film substrate in a pattern that, when the electrode is wrapped around the catheter, leaves two conductive contact surfaces forming the two electrical contacts of the electrode. The remainder of the conductive pattern is overwrapped by an additional layer of polyurethane film during manufacture in order to insulate the traces. The conductive ink used is silver, with the exception of the two electrical contacts of the electrode, which have an additional printed layer of gold ink.

Lead wires are attached that terminate in a safety connector that cannot be connected to an AC power outlet. The Electrode connects to the user's electrodiagnostic equipment. The electrode is to be used under the supervision of a physician. When the urethral catheter with the applied electrode is inserted in the human urethra, the exposed two electrical contacts of the electrode contact the mucosal lining of the urethra in the location of the external urinary sphincter muscle, and the end of the electrode with leadwire attachments are outside of the urethral meatus.

Intended Use

The Signal Gear Urethral Catheter Electrode is intended for mucosal surface stimulation/recording from the external urinary sphincter for use in conjunction with urodynamic evaluation of the patient.

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Traditional 510k –Signal gear Signal Gear Urethral Catheter Electrode

This device is indicated for use in adults, as well as in pediatric patients ages 2 and older.

Technological Characteristics of Device in Relation to Predicate Devices

The Signal Gear Urethral Catheter Electrode is an attachment electrode designed to attach to a urethral (Foley) catheter. It is a printed electrode on a flexible base designed for surface stimulation of and surface recording from physiologic tissue adjacent to the urethra such as the external urinary sphincter muscle. It is self adhesive and is attached during manufacture by wrapping around a urethral (Foley) catheter. It is disposable for single use.

The predicate Dantec 13L40 St Mark's Pudendal Electrode is an attachment electrode, printed on a flexible base designed to stimulate the pudendal nerve and to record from the anal sphincter muscle. It is self adhesive and attaches by wrapping around the finger of a surgical glove. It is disposable for single use.

The technological characteristics of the Signal Gear Urethral Catheter Electrode are substantially equivalent to the predicate device. No new questions of safety or effectiveness are raised.

Summary of Non-Clinical Testing in Support of Substantial Equivalence

Nonclinical testing included inspection for defects in manufacturing, workmanship and packaging, electrical continuity testing and lead wire pull testing.

Biocompatibility was tested according to ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type Hypersensitivity.

Accelerated aging was conducted according to ASTM F1980-07.

Packaging validation tests were conducted according to the methods described in Standards UNI EN ISO 868-5 and 11607–1 and European Standard DIN 58953-6.

The bioburden and sterility tests were conducted according to the methods described in Standards UNI EN ISO 11737-1 and 11737-2.

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

December 13, 2012

Neurovision Medical Products, Inc.
% Ms. Christine Vergély
Regulatory Manager
2225 Sperry Avenue, Suite 1000
VENTURA CA 93003

Re: K113771
Trade/Device Name: Signal Gear Urethral Catheter Electrode
Regulation Number: 21 CFR 876.1620
Regulation Name: Urodynamics measurement system
Regulatory Class: II
Product Code: FAP
Dated: November 29, 2012
Received: November 29, 2012

Dear Ms. Vergély:

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

for

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

Indications for Use

510(k) Number: K113771 (Urethral Surface Electrode)

Device Name: Signal Gear Urethral Catheter Electrode

Indications for Use:

The Signal Gear Urethral Catheter Electrode is intended for mucosal surface stimulation/recording from the external urinary sphincter for use in conjunction with urodynamic evaluation of the patient.

This device is indicated for use in adults, as well as in pediatric patients ages 2 and older.

Prescription Use ___X____ (Part 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113771