K091155

SEP - 8 2009

13. 510(K) SUMMARY

510(k) Summary
for
NeuroMetrix ASCEND

1. SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451

Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: August 17, 2009

2. DEVICE NAME

Proprietary Name: ASCEND
Common/Usual Name: Battery powered peripheral nerve stimulator
Classification Name: 868.2775 BXN Electrical Peripheral Nerve Stimulator

3. PREDICATE DEVICES

- Stockert GmbH Stimuplex HNS 12 (K052313)

4. INTENDED USE

ASCEND is a peripheral nerve stimulator used for localization and verification of needle placement for perineural application of pharmacological agents.

5. DEVICE DESCRIPTION

ASCEND is a battery powered peripheral nerve stimulator. This device is intended for localization and verification of needle placement for perineural application of pharmacological agents.

ASCEND consists of the following components:

5.1 Stimulator

The Stimulator contains the electronic circuitry and software required to electrically stimulate the peripheral nerve. It also contains other functionality such as the user interface.

5.2 Battery

The Stimulator is powered from a high capacity re-chargeable Li-polymer battery. The battery has a nominal voltage of 3.7 V DC and a maximum operating voltage range of 2.75 V to 4.2 V. Its rated capacity is 2140 mAh minimum, 2200 mAh typical. The battery has a built-in safety circuit. The battery is UL recognized.

5.3 Bluetooth

The Stimulator is equipped with a Bluetooth wireless module that provides serial communication between it and other devices.

The Bluetooth module is a Class 1 device that meets the Bluetooth v. 1.2 specifications utilizing the ISM frequency of 2.4 GHz with a variable output power maximum of 12 dBm. The module complies with FCC and CE Marking requirements.

5.4 Charging Station

The Charging Station is used to re-charge the Stimulator's Li-polymer battery.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

ASCEND, which is the subject of this 510(k) Premarket Notification, is substantially equivalent to the predicate Stockert GmbH Stimuplex HNS 12 as previously cleared for marketing. Both ASCEND and the Stockert Stimuplex HNS 12 are used for peripheral nerve localization based on electrical stimulation and have the same Indications for Use.

The technological characteristics of the stimulator in ASCEND and the Stockert GmbH Stimuplex HNS 12 are the same or similar in specification. Based on the verification and validation testing presented, the comparison of ASCEND to the predicate supports a finding of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Mr. Rainer Maas
Director of Quality Assurance/Regulatory Affairs
NeuroMetrix, Incorporated
62 Fourth Avenue
Waltham, Massachusetts 02451

SEP - 3 2009

Re: K091155
Trade/Device Name: ASCEND
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: August 17, 2009
Received: August 19, 2009

Dear Mr. Maas:

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 (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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091155

Device Name: **ASCEND**

Intended Use:

NeuroMetrix ASCEND is a peripheral nerve stimulator used for localization and verification of needle placement for perineural application of pharmacological agents.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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L. Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091155