K 111671 DEC 2 8 2011

510(k) Summary

In accordance with 21CFR807.92

21CFR807.92(a)(1):

Company Name:

SeaSpine, Inc.
2302 La Mirada Drive
Vista, CA 92081

Contact person:

Dan Miller
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Date prepared:

June 13, 2011

21CFR807.92(a)(2):

Trade name:

SeaSpine Monopolar Probe System
(Trade name has not been finalized at this time)

Common name:

Nerve Stimulator

Classification:

Surgical Nerve Stimulator/locator
21 CFR 874.1820
Class II

Product Code:

ETN

21CFR807.92(a)(3):

Predicate Device:

Manufacturer: Medtronic Xomed
Trade Name: Stimulus Dissection Instruments
Product Code: ETN
510(k): K014165

Manufacturer: Nuvasive
Trade Name: Nuvasive Neurovision JJB System
Product Code: ETN, GWF
510(k): K051718

21CFR807.92(a)(4):

Device Description:

The SeaSpine Monopolar Probes conduct electrical stimulation to nervous tissue that may be present in close proximity of the surgical corridor to the spine. This system is not comprised of a nerve stimulator or recorder; instead it will use conventional stimulators found in the market. The SeaSpine Monopolar Probes are insulated by a biocompatible PEEK (polyetheretherketone) layer all around one or more conductive stainless steel wire(s) with the exception of the distal and proximal ends. The distal end contacts the target tissue and the proximal end connects to standard intraoperative neuromonitoring monopolar stimulator that offers triggered electromyography (EMG) capability. Triggered EMG is a standard intraoperative practice where motor nerves are stimulated and their

corresponding muscle group response is recorded, allowing for avoidance of nervous tissue during surgical approach. The proximal connector design meets the requirements of IEC 60601-1:1988 /A1:1991 /A2:1995 Clause 56.3(c) per 21 CFR 898.12.

21CFR807.92(a)(5):
Intended use:

The SeaSpine Monopolar Probe System is indicated for tissue dilation and nervous tissue stimulation by means of electrical current to assess location and identification of motor nerves (including spinal nerve roots) for nervous tissue avoidance during a routine surgical approach to the spine.

21CFR807.92(a)(6):
Substantial Equivalence:

The SeaSpine Monopolar Probe System has indications for use which are substantially equivalent to those of the predicate devices and other legally marketed devices. The SeaSpine Monopolar Probe System is manufactured from similar or identical materials as the predicate devices. The design features and function of the SeaSpine Monopolar Probe System are substantially equivalent or the same to predicate devices and other legally marketed devices, and the SeaSpine Monopolar Probe System does not raise any new safety or effectiveness issues.

Technological Characteristic	Subject Device	Medtronic Xomed Stimulus Dissection Instruments (K014165)	Nuvasive NeuroVision JJB System (K051718)
Indications For Use	The SeaSpine Monopolar Probe System is indicated for tissue dilation and nervous tissue stimulation by means of electrical current to assess location and identification of motor nerves (including spinal nerve roots) for nervous tissue avoidance during a routine surgical approach to the spine.	Tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	The NeuroVision JJB System is used for intraoperative monitoring and neurological status assessment by the administration of brief electrical stimulus pulses to neural tissues and the EMG monitoring of the associated muscle groups. The system is used in conjunction with other Nuvasive devices to assist in gaining controlled access to, and visualization of, the spine.

Design	Electrical Conduit insulated all around with exception to distal tip and proximal connector	Electrical Conduit insulated all around with exception to distal tip and proximal connector	Electrical Conduit insulated all around with exception to distal tip and proximal connector
Electrical Conduction Material	Stainless Steel	Stainless Steel	Stainless Steel or Aluminum
Electrical Patient Contact Surface	Stainless Steel	Stainless Steel	Stainless Steel or Aluminum
Proximal Stimulator Connector	Yes	Yes	Yes
Biocompatible plastic electrical insulation	Yes	Yes	Yes
Steam Sterilizable /Reusable	Yes	Yes	Yes*

*also cleared for disposable probes.

21CFR807.92(b)(1)(2):
Disscussion :

The biocompatibility of the subject device was assessed per ISO 10993. The biocompatibility of the adhesive used internally was assessed per USP Class VI testing. The probes are manufactured from stainless steel and PEEK with a long track record of use in the medical device industry and in instruments that directly contact tissue. The tissue contact duration of the SeaSpine Monopolar Probe System is brief (<1 hour), and this level of testing far exceeds the requirements for similar instruments and contact duration per ISO 10993-1. Electrical Safety of the SeaSpine Monopolar Probe System conforms to IEC 60601-1:1988 /A1:1991 /A2:1995 Clause 56.3(c) per 21 CFR 898.12.

21CFR807.92(b)(3):
Conclusions:

Engineering analysis, specifications, and labeling have established that the SeaSpine Monopolar Probe System is similar or identical to legally marketed predicates in terms of indications for use, materials, design, and functionality. Therefore, we have demonstrated that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SeaSpine, Inc.
% Mr. Dan Miller
2302 La Mirada Dr
Vista, CA 92081-7862

DEC 2 8 2011

Re: K111671
Trade Name: SeaSpine Monopolar Probe System
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: November 28, 2011
Received: November 30, 2011

Dear Mr. Miller:

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111671

Device Name: SeaSpine Monopolar Probe System

Indications for Use:

The SeaSpine Monopolar Probe System is indicated for tissue dilation and nervous tissue stimulation by means of electrical current to assess location and identification of motor nerves (including spinal nerve roots) for nervous tissue avoidance during a routine surgical approach to the spine.

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)

Dr Binoy Mathews

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111671