K063305

510(k) Summary

NOV 2 9 2006

510(k) Owner	Medtronic Xomed, Inc 6743 Southpoint Drive North Jacksonville, Florida 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
Contact Name	Antoine Kouchakjy Senior Regulatory Affairs Specialist Medtronic Xomed, Inc
Date Summary Prepared	October 31, 2006
Proprietary Name	Stimulating Bur Guard (Final name TBD)
Common Name	Stimulator, Nerve

Classification Name

Primary • Surgical nerve stimulator / locator
(21 CFR 874.1820, Product Code ETN, Class II)

Secondary • Drill, Surgical, ENT (electric or pneumatic) including handpiece
(21 CFR 874.4250, Product Code ERL, Class II)

Secondary • Surgical instrument motors & accessories / attachments
(21 CFR 878.4820, Product Code HWE, Class I)

Marketed device claiming equivalence to:

The Stimulating Bur Guard is equivalent to the Medtronic Xomed Monopolar Stimulator Probe, K992869. The guard is also an accessory to the XPS 3000 Drill System covered under K041523.

Device Description

The Stimulating Bur Guard is a sterile, single use device used in conjunction with the XPS 3000 BF Powered Drill System and the Medtronic Xomed Nerve Monitoring System. It locks onto a handpiece and has an opening on the anterior end to accept a standard bur / blade. The primary purpose of the Stimulating Bur Guard is to deliver the stimulating current from the Nerve Monitoring console to the standard bur / blade on the drill handpiece. The second purpose of the Stimulating Bur Guard is to provide support for the extended length burs.

Intended Use

When used with both the Medtronic Nerve Integrity Monitor (NIM) and XPS Drill Systems, the Stimulating Bur Guard is intended to stimulate cranial and peripheral motor nerves, including spinal nerve roots, with a standard bur / blade for location and identification during the incision and removal of soft and hard tissue or bone.

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Indications for Use

The Stimulating Bur Guard is indicated for nerve monitoring during the incision and removal of soft and hard tissue or bone with a standard bur / blade during otology, neurotology, sinus, laryngeal, nasopharyngeal, head and neck, general and plastic, and orthopedic surgical procedures, including spinal applications.

Summary of Technological Characteristics

Characteristic	New Device: Medtronic Xomed Stimulating Guard	Predicate: Medtronic Xomed Ball-Tip Monopolar Stimulating Probe [K992869]
Intended use	When used with both the Medtronic Nerve Integrity Monitor (NIM) and XPS Drill Systems, the Stimulating Guard is intended to stimulate cranial and peripheral motor nerves, including spinal nerve roots, with a standard bur / blade for location and identification during the incision and removal of soft and hard tissue or bone.	To stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots
Insulated	Yes	Yes
Stimulator connector	Yes	Yes
Biocompatible	Yes	Yes
Sterile	Yes	Yes
Sterilization Method	ETO	ETO
Shelf Life	3 months (initially)	8-year
Single Use	Yes	Yes
Monopolar	Yes	Yes

Biocompatibility

The Stimulating Guard is considered biocompatible for use as an external communicating device with tissue / bone contact of limited duration (< 24 hrs). The appropriate tests were performed on all patient contacting materials according to:

- ISO 10993-1:2003, Biological evaluation of medical devices – Part 1 Evaluation and Testing
- FDA G95-1, Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995

Shelf Life Aging

Accelerated aging studies for the Stimulating Guard will ensure three (3) months shelf life prior to a limited market release and a minimum shelf life of one (1) year at the time of full market release. Shelf life testing will be ongoing post-launch to ultimately achieve a four (4) year shelf life.

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Operating Life

The device is provided sterile and intended for single use. No reprocessing instructions are given. The device met the acceptance criteria for worst case use during a surgical procedure.

Bench Testing

The device met the acceptance criteria for: Reliability and Useful life, Bur / blade Compatibility, Current delivery, Current delivery compared to 2.3mm ball tip probe, Noise, Temperature, Current drop out, Electrical Isolation

Electromagnetic Compatibility and Electrical Safety Testing

The Stimulating Guard is not a source of electromagnetic interference in and of itself. However, the devices are evaluated for EMC as a system with the nerve monitoring and drill system consoles in accordance with EN 60601-1-2. Electrical safety testing is conducted in accordance with EN / IEC 60601-1 and electrical safety is achieved through levels of protection built within the BF Rated Consoles. Both the XPS 3000 and NIM systems are BF rated.

Software

The device does not contain any software nor does it require any software changes to be made to the XPS Drill System or the Nerve Monitoring System (NIM)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Xomed, Inc.
c/o Antoine Kouchakjy
Senior Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216-0980

NOV 29 2006

Re: K063305
Trade/Device Name: Stimulating Bur Guard
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: October 31, 2006
Received: November 1, 2006

Dear Mr. Kouchakjy:

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 such 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.

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 (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

M B Eydelman, MD

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K063305

Device Name: Stimulating Bur Guard (Final name to be determined)

Indications for Use:

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The Stimulating Bur Guard is indicated for nerve monitoring during the incision and removal of soft and hard tissue or bone with a standard bur / blade during otology, neurotology, sinus, laryngeal, nasopharyngeal, head and neck, general and plastic, and orthopedic surgical procedures, including spinal applications.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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Prescription Use X
(Per 21 CFR 801.109)