FEB 27 2009

K083124

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
Nerve Integrity Monitor 3.0

510(k) Owner	Medtronic Xomed, Inc 6743 Southpoint Drive North Jacksonville, Florida 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
Contact Name	Jayme Wilson Senior Regulatory Affairs Specialist Medtronic Xomed, Inc
Date Summary Prepared	October 21, 2008
Proprietary Name	Nerve Integrity Monitor 3.0 (Final name TBD)
Common Name	Nerve Stimulator
Classification Name	Evoked response electrical stimulator (21 CFR 882.1870, Product Code GWF, Class II) Surgical nerve stimulator/locator (21 CFR 874.1820, Product Code ETN, Class II)

Marketed device claiming equivalence to

The Medtronic Nerve Integrity Monitor 3.0 and accessories are substantially equivalent to the Medtronic NIM Spine (K031510) and the NIM PRS (K024316).

Device Description

NIM 3.0 is a multi-channel intraoperative neurophysiological monitor capable of connecting various styles of patient monitoring electrodes and supplying electrical stimulus for evoked responses. The monitoring console uses both video and audio output. Responses monitored with the device may originate from operator applied electrical stimulus or from direct or indirect mechanical stimulus occurring during the course of the surgery.

Intended Use

The NIM 3.0 is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal cord and spinal nerve roots. The APS electrode is an accessory intended for providing automatic periodic stimulation to nerves when used with the Medtronic Nerve Monitoring Systems.

Indications for Use

Indications for NIM 3.0 EMG Monitoring Procedures include:
Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities

Indications for Spinal procedures which may use NIM 3.0 EMG monitoring include:
Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery, Open and Percutaneous Lumbar and Cervical Surgical Procedures, and Thoracic Surgical Procedures.

Substantial Equivalence

The indications, design, technology, functions, and principle of operation of the NIM 3.0 are substantially equivalent to the NIM Spine (K031510) and the NIM PRS (K024316).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2009

Medtronic Xomed, Inc.
% Ms. Jayme Wilson
Senior Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, FL 32216-0980

Re: K083124
Trade/Device Name: Xomed Nerve Integrity Monitor 3.0
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, ETN
Dated: February 17, 2009
Received: February 18, 2009

Dear Ms. Wilson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: ____Nerve Integrity Monitor 3.0 (Final name to be determined)____

Indications for Use:

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Indications for NIM 3.0 EMG Monitoring Procedures include:
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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 General, Restorative, and Neurological Devices

510(k) Number K083124