K031510

JUN 18 2003

510(k) Summary

1.0 Date Prepared

March 22, 2003

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	NIM Spine (The tradename has not been finalized at this time)
Common Name(s):	Nerve Integrity Monitor, Intraoperative Electromyographic (EMG) Monitor, Nerve locator / stimulator
Classification Name(s):	Nerve locator / stimulator, Electromyographic (EMG) Monitor

4.0 Device Classification

Classification Name:	Nerve locator / stimulator,	Electromyographic (EMG) Monitor
Procode 77ETN	Class II	21 CFR § 874.1820
Procode 89IKN	Class II	21 CFR § 890.1375
Procode 84GWF	Class II	21 CFR § 882.1870

5.0 Device Description

NIM Spine 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. Acquired data may be stored on various types of durable media, and hard copy may be obtained via an optional printer.

6.0 Indications for Use

This device is intended for use in surgical procedures for patient-connected intraoperative nerve monitoring, i.e. assisting the surgeon in locating and mapping motor nerves through the use of electromyographic (EMG) signals and electrical stimulus of nerves. This device is indicated for locating and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots.

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510(k) Summary *(continued)*

7.0 Substantial Equivalence

The indications, basic instrumentation, design, technology, system features, functions, and principle of operation of the NIM Spine are substantially equivalent to the Nicolet Viking IV, (K923315, 890495, K880573,K842956) described as used with the Nicolet Bravo system, (K991054) and Neurosign 800 devices.

The Monopolar Stimulating Instrumentation is equivalent to Medtronic Xomed's Stimulus / Dissection Instrumentation, cleared via K014165.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2003

Medtronic Xomed
c/o Mr. Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K031510
Trade/Device Name: NIM Spine
Regulation Number: 21 CFR 874.1820, 21 CFR 890.1375, 21 CFR 882.1870
Regulation Name: Surgical nerve stimulator/locator
Diagnostic electromyography
Evoked response electrical stimulator
Regulatory Class: II
Product Code: ETN, IKN, GWF
Dated: June 9, 2003
Received: June 9, 2003

Dear Mr. Mosenkis:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAY 12 2003

510(k) Number (if known): K031510
Device Name: NIM Spine
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031510

Prescription Use _____ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)