

**510(k) Summary
NIM Monitor**

1.0 Date Prepared
July 22, 1998

2.0 Submitter (Contact)
David Timlin
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name
Proprietary Name: NIM4
(The product's trade name has not been finalized and may be changed at a later date.)

Common Name(s): Nerve Integrity Monitor, Intraoperative Electromyographic (EMG) Monitor, Nerve locator / stimulator

Classification Name: Nerve locator / stimulator, Electromyographic (EMG) Monitor

4.0 Device Classification
Nerve locator / stimulator
Procodel 77 ENT Class II ; 21 CFR 874.1820

Electromyographic (EMG) Monitor
Procodel 89 CAB Class II ; 21 CFR 874.4140

5.0 Device Description
The purpose of this 510(k) is to notify the FDA of changes that are intended to be made to the currently marketed NIM-2XL Nerve Integrity Monitor. As previously mentioned, these changes serve to improve the NIM-2XL even further: to make the device more "user friendly" and simplify its use, provide a cleaner, higher quality signal, provide additional options for documentation (printer, disk drive, and video-out) and to lower the overall cost of the system through the use of state-of-the-art componentry. Other than the changes specifically described in this notification, the device remains the same as previously provided in K934426.

6.0 Intended Use
This device is indicated 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.

7.0 Substantial Equivalence

The added features described in this notification do not present any significant differences when compared to the currently marketed NIM-2XL Nerve Integrity Monitor. They do not change the intended use of the device and only serve to compliment the current system operation. The Hazard Analysis, included with the software validation, confirms that the proposed modifications present no greater risks than those associated with the current system. If anything, it is expected that the majority of the changes will aid in lowering the risk through simplification of use and cleaner signals.

Conclusion: The proposed NIM4 Nerve Integrity Monitor that is described in this notification, has the same intended use and the same basic technological characteristics as the previously cleared device; and, does not raise any new issues of safety or effectiveness.



SEP - 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850David Timlin
Manager, Regulatory Affairs
Xomed, Inc.
6743 Southpoint Drive, N.
Jacksonville, Florida 32216-0980Re: K982595
NIM (Nerve Integrity Monitor)
Dated: July 24, 1998
Received: July 27, 1998
Regulatory Class: II
21 CFR 874.1820/Procode: 77 ETN

Dear Mr. Timlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

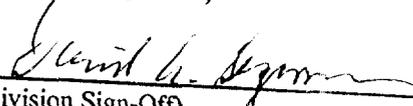
Device Name: NIM Monitor

Indications for Use:

This device is indicated 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K982595

Prescription Use
(Per 21 CFR 801.109)

Or

Over-the-Counter Use

(Optional Format 1-2-96)