

K112 686

JUN 27 2012

### Section 5.0 510(k) Summary

**A. 510(k) Owner** Medtronic Xomed, Inc  
6743 Southpoint Drive North  
Jacksonville, Florida 32216-0980 USA  
904-279-7586  
904-296-2386 (FAX)

**B. Contact Information** Marek Pawlowski  
Senior Regulatory Affairs Specialist  
Medtronic Xomed, Inc  
[marek.pawlowski@medtronic.com](mailto:marek.pawlowski@medtronic.com)

**C. Date Summary Prepared** November 10, 2011

**D. Proprietary Name** Next Gen EMG Endotracheal Tube

**E. Device Name**

**Trade name:** Next Gen EMG Endotracheal Tube (final name TBD)  
**Common/Usual Name:** EMG ET Tube, EMG Endotracheal Tube  
**Classification Name:** Surgical nerve stimulator/locator  
(21 CFR 874.1820, Product Code ETN, Class II)

**F. Predicate Devices:**

**Trade Name:** NuVasive® NeuroVision® EMG Endotracheal Tube  
**Common/Usual Name:** EMG ET Tube  
**Classification Name:** Surgical nerve stimulator/locator  
(21 CFR 874.1820, Product Code ETN, Class II)  
**Premarket Notification:** K094054

**Trade Name:** Xomed EMG Endotracheal Tube  
**Common/Usual Name:** EMG ET Tube  
**Classification Name:** Surgical nerve stimulator/locator  
(21 CFR 874.1820, Product Code ETN, Class II)  
**Premarket Notification:** K925640

**G. Purpose of Submission:**

Design change in the material of the tube from silicone in the predicate device Xomed EMG Tube to PVC in the proposed device and design change of electrodes from stainless steel wire in the predicate device to conductive silver ink in the proposed device.

**H. Device Description**

The Next Gen EMG Endotracheal Tube is a standard-size PVC (DEHP-free polyvinyl chloride) endotracheal tube with inflatable high volume, low pressure cuffs. Each tube is imprinted with four (two pairs) conductive silver electrodes. The conductive silver is printed on the PVC of the main shaft of the endotracheal tube and exposed only for a short distance, approximately 40 mm, slightly superior to the cuff, for contacting the vocal cords. The electrodes are designed to make contact with the patient's vocal cords to facilitate electromyographic (EMG) monitoring of the laryngeal musculature during surgery when connected to a multi-channel EMG neuromonitoring device.

**I. Intended Use/Indications for Use:**

***Indications for Use:***

The EMG Tube is indicated for use when continuous monitoring of the integrity of the nerves supplying the laryngeal musculature is required during surgical procedures.

***Intended Use:***

The Next Generation EMG Endotracheal Tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the laryngeal musculature when connected to an appropriate EMG monitor.

**J. Substantial Equivalence**

The subject device: Next Gen EMG Endotracheal Tube is substantially equivalent to predicate devices cleared by FDA for commercial distribution in the United States. A comparison of technological characteristics in areas including design, material composition, function, packaging and sterilization is presented in the table below:

	Subject Device Next Gen EMG Endotracheal Tube	Predicate Device(s)	
		NuVasive® NeuroVision® EMG Endotracheal Tube (K094054)	Xomed EMG Endotracheal Tube (K925640)
Laryngeal Surface Electrode	Yes	Yes	Yes
Endolaryngeal Location	Yes	Yes	Yes
Number of Electrodes	4	4	4
Electrode Surface Material	Conductive Silver Ink	Conductive Silver Ink	Stainless Steel Wire
Tube & Cuff Material	PVC	PVC	Silicone
Reinforcing Material	None	None	Stainless Steel Wire
Tube Dimensions	Various Dimensions	Various Dimensions	Various Dimensions
Sterilization & Packaging	Sterile, single use only	Sterile, single use only	Sterile, single use only

**K. Conclusion**

In house laboratories conducted studies verifying the design of the proposed device. Studies followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Nonclinical testing was performed to demonstrate that the proposed Next Gen EMG Tube is substantially equivalent to the predicate devices.

The following testing was performed:

- Biocompatibility testing per ISO 10993-1 requirements, including:
  - cytotoxicity testing (per ISO 10993-5:2009)
  - intracutaneous reactivity testing (per ISO 10993-10:2010)
  - sensitization testing (per ISO 10993-10:2010)
  
- Functional testing, including:
  - compliance testing per ISO 5361:1999
  - electrode impedance test
  - wire harness test
  - product integration testing
  - marking ink adhesion test.

Functional testing was performed using an animal model. The animal study provided evidence that the proposed device performed substantially equivalent to the predicate devices during monitoring of nerve integrity during surgical procedures.

The data presented in this Premarket Notification support that the subject device is safe and effective and performs in the same manner as the predicate devices when used in accordance with the labeled directions for use and for the specified indication(s).

The risks of the subject device, as well as the benefits to the patient, are the same as those attributed to the use of the predicate devices.

A direct comparison of key technological characteristics demonstrates that the proposed Next Gen EMG Endotracheal Tube is substantially equivalent to the predicate devices in areas including design, material composition, function, packaging and sterilization.



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

Medtronic Xomed  
c/o Mr. Marek Pawlowski  
Senior Regulatory Affairs Specialist  
6743 Southpoint Dr. North  
Jacksonville, FL 32216

JUN 27 2012

Re: K112686

Trade/Device Name: Next Generation EMG Endotracheal Tube  
Regulation Number: 21 CFR 874.1820  
Regulation Name: Surgical nerve stimulator/locator  
Regulatory Class: Class II  
Product Code: ETN  
Dated: June 15, 2012  
Received: June 18, 2012

Dear Mr. Pawlowski:

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 and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K112 686

**Section 4.0 Indications for Use Statement**

**Indications for Use**

510(k) Number (if known): K112686

Device Name: Next Generation EMG Endotracheal Tube (Final name to be determined).

Intended Use/Indications for Use:

The Next Generation EMG Endotracheal Tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the laryngeal musculature when connected to an appropriate EMG monitor.

The EMG Tube is indicated for use when continuous monitoring of the integrity of the nerves supplying the laryngeal musculature is required during surgical procedures.

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)

John D. Dewart  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K112686

X  
Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)