October 26, 2023

Medtronic Xomed, Inc.
Emily Davis
Principal Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K230320
Trade/Device Name: NIM Standard Reinforced EMG Endotracheal Tube; CONTACT Reinforced EMG Endotracheal Tube
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: August 29, 2023
Received: August 30, 2023

Dear Emily Davis:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230320

Device Name
NIM™ Standard Reinforced EMG Endotracheal Tube and NIM CONTACT™ Reinforced EMG Endotracheal Tube

Indications for Use *(Describe)*
The EMG tube is indicated for use where continuous monitoring of the nerves supplying the laryngeal musculature is required during surgical procedures. The EMG tube is not intended for postoperative use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) Summary was prepared in accordance with 21 CFR 807.92.

Submitted By:	Medtronic Xomed, Inc. 6743 Southpoint Drive North Jacksonville, Florida 32216 USA Telephone Number: (904) 296-9600
510(k) Number:	K230320
Date Prepared:	10/26/2023
Official Correspondent:	Alexandra Oliver Regulatory Affairs Manager Telephone: (904) 332-8936 Email Address: Alexandra.j.oliver@medtronic.com
Alternate Contact:	Emily Davis Principal Regulatory Affairs Specialist Telephone: (949) 636-4621 Email Address: emily.r.davis@medtronic.com

I. DEVICE

Proprietary (Trade) Names:	NIM™ Standard Reinforced EMG Endotracheal Tube, NIM CONTACT™ Reinforced EMG Endotracheal Tube
Common Name:	Stimulator
Regulation Name:	Surgical nerve stimulator/locator
Regulation Number:	21 CFR 874.1820
Product Code:	ETN
Device Classification:	II
Review Panel:	Ear, Nose, & Throat (ENT)

II. PREDICATE DEVICE(S)

The NIM™ Standard Reinforced EMG Endotracheal Tube and NIM CONTACT™ EMG Reinforced Endotracheal Tube are substantially equivalent in intended use and technological characteristics to the following predicate device(s):

510(k) Number	510(k) Device Name	Product Code	Regulation Number	510(k) Clearance Date
K925640	Xomed-Treace EMG Endotracheal Tube	ETN	21 CFR 874.1820	August 17, 1993
K050162	CONTACT™ EMG Rotatable Endotracheal Tube	ETN	21 CFR 874.1820	March 3, 2005

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III. DEVICE DESCRIPTION

Device Description

Medtronic Xomed, Inc.'s NIM™ Standard Reinforced and NIM CONTACT™ Reinforced Endotracheal Tubes are flexible, reinforced endotracheal tubes with inflatable cuffs. The NIM EMG ET Tubes are made from silicone elastomer. Each tube is fitted with electrodes on the main shaft, which are exposed only for a short distance, slightly superior to the cuff. The electrodes are designed to make contact with the laryngeal muscles around the patient's vocal cords to facilitate electromyographic (EMG) monitoring of the laryngeal musculature during surgery when connected to an EMG monitoring device. Both the tube and cuff are manufactured from material that allows the tube to conform readily to the shape of the patient's trachea with minimal trauma to tissues.

Intended Use

The 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 intrinsic laryngeal musculature when connected to an appropriate EMG monitor.

IV. INDICATIONS FOR USE

Indications for Use

The EMG tube is indicated for use where continuous monitoring of the nerves supplying the laryngeal musculature is required during surgical procedures. The EMG tube is not intended for postoperative use.

V. TECHNOLOGICAL COMPARISON TO THE PREDICATE DEVICE(S)

The EMG Endotracheal tube is substantially equivalent to the predicate devices based on comparison of indications for use and technological characteristics where additions to the subject devices instructions for use were made being the only difference. Technological Characteristics of our device compared to each predicate is shown in the following table and in the Substantial Equivalence section of this submission.

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Feature/Attribute	NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube (Subject Device(s))	Xomed-Treace EMG Endotracheal Tube / K925640 (Predicate Device)	CONTACT™ EMG Rotatable ET Tube / K050162 (Predicate Device)
Product Code	ETN	ETN	ETN
Regulation Number	21 CFR 874.1820	21 CFR 874.1820	21 CFR 874.1820
Regulation Description	Surgical nerve stimulator/locator	Surgical nerve stimulator/locator	Surgical nerve stimulator/locator
Classification	Class II	Class II	Class II
Common Name	Nerve Stimulator	Nerve Stimulator	Nerve Stimulator
Indications for Use	The EMG tube is indicated for use where continuous monitoring of the nerves supplying the laryngeal musculature is required during surgical procedures. The EMG tube is not intended or postoperative use.	Intraoperative electromyographic monitoring of the vocal cords to facilitate locating and mapping of the recurrent laryngeal nerve in surgical procedures involving the laryngeal region of the throat.	The CONTACT™ EMG Rotatable 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 intrinsic laryngeal musculature when connected to an appropriate EMG monitor. The EMG Tube is indicated for use where continuous monitoring of the integrity of the nerves supplying the laryngeal musculature is required during surgical procedures.
Tube Lengths	Approximately 12.8 inches	Approximately 12.8 inches	Approximately 12.8 inches
Tube Inner Diameter (ID)	6mm-8mm	4mm-8mm	6mm-8mm
Number of Laryngeal Surface Electrodes	4	4	4
Electrode Surface	Stainless steel wire	Stainless steel wire	Stainless steel wire
Tube Material	Silicone	Silicone	Silicone
Cuff Material	Silicone	Silicone	Silicone
Reinforcing Material	Stainless Steel	Stainless Steel	Stainless Steel
Sterilization Method	EtO	EtO	EtO
Tube Lengths	Approximately 12.8 inches	Approximately 12.8 inches	Approximately 12.8 inches
Tube Inner Diameter (ID)	6mm-8mm	4mm-8mm	6mm-8mm
Number of Laryngeal Surface Electrodes	4	4	4
Electrode Surface	Stainless steel wire	Stainless steel wire	Stainless steel wire
Tube Material	Silicone	Silicone	Silicone
Cuff Material	Silicone	Silicone	Silicone
Reinforcing Material	Stainless Steel	Stainless Steel	Stainless Steel
Sterilization Method	EtO	EtO	EtO

Substantial Equivalence Discussion

The purpose of this submission is to gain clearance for proposed modifications to the labeling (Instructions for Use (IFU) and product labels) for the NIM™ Standard Reinforced and NIM CONTACT™ Reinforced Endotracheal Tubes. The NIM™ EMG ET Tubes are intended for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the intrinsic laryngeal musculature when connected to an appropriate EMG monitor. As the intended use remains the same, the differences in labeling between the subject and predicate devices are additional warnings and precautions in the IFU for actions to be taken if airway obstruction is encountered, with additional symbols on product labeling for clarification on EMG ET Tube material and recommended tool for cuff inflation. These modified labeling differences are critical to the intended surgical use of the device when used as labeled and have been evaluated by Human Factors Testing and a Labeling Design Validation study which were found to improve the safety and efficacy. Both the subject device(s) and the predicate device(s) share similar characteristics (design, materials, operating principle, energy source, and performance).

VI. PERFORMANCE DATA

Performance Testing Discussion

The following nonclinical testing was performed to establish substantial equivalence to the predicates: Summative Usability Validation and Labeling Design Validation. The Objective of this Summative Usability Validation testing was to accomplish:

1. Achieve the Usability Goal: The Anesthesiologist/Nurse Anesthetist shall be able to intubate the patient and maintain the airway without introducing any unrealized use errors or critical tasks;
2. Confirm the Critical tasks were completed without any unacceptable Use Error that may have resulted in unmitigated potential hazards; and
3. To show the risk mitigations were effective in regard to labeling and training.

Additionally, the objective of the Labeling Design Validation was to validate that the NIM EMG Tube IFU and product labels met the User Need which was that the product labeling was to be understandable and provide needed information for proper safe and effective use of the device.

The results of these validations with the modified proposed labeling demonstrated that the usability goal was achieved, all critical tasks were completed without introducing any additional unmitigated hazards, the user need and risk control measures were met and the training mitigations proposed were effective. This nonclinical testing demonstrated that the subject device is substantially equivalent to the predicate device.

Clinical Testing

No clinical test data is required of the proposed device.

VII. CONCLUSION

The NIM™ Standard Reinforced and NIM CONTACT™ Reinforced Endotracheal Tubes is concluded to be substantially equivalent to the predicates as the identified differences do not raise new or different concerns or questions of safety and effectiveness relative to the predicate device(s). Therefore, it is the opinion of the submitter that the NIM™ Standard Reinforced and NIM CONTACT™ Reinforced Endotracheal Tubes are as safe, as effective and performs as well as the legally marketed predicated devices.