February 10, 2026

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

Re: K251672
Trade/Device Name: NIM Essence™ EMG Endotracheal Tube
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: May 30, 2025
Received: May 30, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Joyce C. Lin -S

for 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)*
K251672

Device Name
NIM Essence™ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Company (submitter): Medtronic Xomed, Inc.
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Jacksonville, Florida 32216 USA
Telephone Number: (904) 296-9600

Date Prepared: February 9, 2026

510(k) Number K251672

Official Correspondent: Emily Davis
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I. DEVICE

Proprietary (Trade) Name:	NIM Essence™ EMG Endotracheal Tube
Common Name:	Stimulator, Nerve
Regulation Name:	Surgical nerve stimulator/locator
Regulation Number:	21 CFR 874.1820
Product Code:	ETN
Classification:	2
Panel:	Ear, Nose, & Throat (ENT)

II. PREDICATE DEVICE

The NIM Essence™ Endotracheal Tube are substantially equivalent in intended use and technological characteristics to the following predicate device:

510(k) Number	510(k) Device Name	510(k) Clearance Date
K112686	NIM Trivantage™ EMG Endotracheal Tube	June 27, 2012

NOTE: Product under K112686 was submitted and cleared under the trade name "Next Gen EMG Endotracheal Tube (final name TBD)" where the final name was determined to be "NIM Trivantage™" shortly after 510(k) clearance.

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III. DEVICE DESCRIPTION

The Medtronic NIM Essence™ EMG Endotracheal Tube (ETT) is a flexible, reinforced PVC endotracheal tube with an inflatable cuff. FPC (Flexible Printed Circuit) is attached and wrapped around the main shaft of the endotracheal tube, and silicone cover tube overlays on the FPC. The FPC electrodes are exposed only for a short distance, approximately 30 mm, 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 the cuff are manufactured from material that allows the tube to readily conform to the shape of the patient's trachea with minimal trauma to tissues. The NIM Essence™ EMG Endotracheal Tube is packaged as a sterile single-use device.

The Medtronic NIM™ 3.0 (cleared via K083124 on February 27, 2009) and NIM Vital™ (cleared via K200759 on October 28, 2020) nerve monitors are the recommended EMG monitors for use with the EMG Endotracheal Tube. All references to connections and technical specifications for EMG monitor contained in the instructions are made with references to the NIM™ family of devices. Medtronic recommends that the user consult the NIM™ User's Guide for determining proper settings of the NIM™ console and instructions for intraoperative EMG monitoring and motor nerve location and stimulation. The NIM Essence™ EMG Endotracheal Tube is Type BF applied part.

IV. 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.

V. 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.

VI. SUBSTANTIAL EQUIVALENCE

The EMG Endotracheal tube is substantially equivalent to the predicate device 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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Substantial Equivalence/Device Comparison

Feature/Attribute	NIM Essence™ EMG Endotracheal Tube (Subject Device)	NIM Trivantage™ EMG Endotracheal Tube / K112686 (Predicate Device)	Comparison
Product Code	ETN	ETN	Same
Regulation Number	21 CFR 874.1820	21 CFR 874.1820	Same
Regulation Description	Surgical nerve stimulator/locator	Surgical nerve stimulator/locator	Same
Classification	Class II	Class II	Same
Common Name	Stimulator, Nerve	Stimulator, Nerve	Same
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.	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.	Same
Single Use	Yes	Yes	Same
Shelf Life	3 Years	4 Years	Difference, see below discussion 1
Principles of Operation	Electrical stimulation	Electrical stimulation	Same
Tube Inner Diameter (ID)	6mm-8mm	5mm-9mm	Similar, the subject device provides the tube inner diameter size within the range of the predicate device.

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Feature/Attribute	NIM Essence™ EMG Endotracheal Tube (Subject Device)	NIM Trivantage™ EMG Endotracheal Tube / K112686 (Predicate Device)	Comparison
Number of Laryngeal Surface Electrodes	4	4	Same
Electrode Surface Material	Flexible Printed Carbon Overprint	Conductive Silver Ink	Difference, see below discussion 2
Tube Material	PVC	PVC	Same
Cuff Material	PVC	PVC	Same
Reinforcing Material	Stainless Steel	None	Difference, see below discussion 3
Sterilization Method	EtO	EtO	Same
Duration of Use	Limited (less than 24 hours)	Limited (less than 24 hours)	Same
Biocompatibility	Yes, according to ISO 10993-1 and ISO 18562-1	Yes, according to ISO 10993-1 and ISO 18562-1	Same

Difference Discussion 1:
The subject device NIM Essence™ EMG Endotracheal Tube declares 3 years as the shelf life. Accelerating aging test report and real time aging test report have proved 3 years shelf life of the subject device. Package accelerating aging test report and package real time aging test report prove that the subject device package can maintain a sterile barrier for the entirety of the proposed shelf-life. There is no impact of the shelf life difference to the device safety or performance.

Difference Discussion 2:
Firstly, the flexible printed circuit (FPC) as a part of NIM Essence EMG endotracheal tube is biocompatible and it can meet the requirements for biological safety performance. The NIM Essence tube complies with ISO 10993-1 and FDA biocompatibility guidance 2023. Cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity tests are performed on the subject device to find it is biocompatible.

Secondly, NIM Essence EMG endotracheal tubes with FPC design are assessed for electrical safety and electromagnetic compatibility and can meet ANSI AAMI ES 60601-1/IEC 60601-1, IEC 60601-1-2 and IEC TS 60601-4-2.
Thirdly, NIM Essence EMG endotracheal tubes with FPC design can comply with IEC 60601-1-6 and IEC 62366-1. NIM Essence EMG Tube Usability Engineering Plan and Summary Report proves that NIM Essence EMG tube has been found to be adequately safe and effective for the intended users, uses and use environments.

Difference Discussion 3:
The difference in the design of the subject device and predicate device is in the reinforcement. The subject device uses the stainless steel as the reinforcing material to make tube more rigid, thus, reduces softness. The technological characteristic differences do not affect safety and effectiveness as demonstrated through performance testing. The NIM Essence™ EMG endotracheal tube shall not kink after bending the tube 90° around a pre-defined 30mm radius of curvature. For the collapse test, the specified steel ball shall pass freely through the NIM Essence tube after conditionings. The reinforcing material is to make the tube more rigid. The stainless steel used as the reinforcing material in the Medtronic endotracheal tubes for more than 30 years. Moreover, PVC tube with stainless steel reinforcing material from Well Lead Medical was cleared under K073383 on July 10, 2008. Well Lead Medical manufactures a similar PVC tube with stainless steel reinforcing material. The bench testing performed verifies that the performance and materials of the subject device are substantially equivalent in terms of critical performance characteristics to the predicate device.

VII. PERFORMANCE DATA

The following non-clinical testing was performed to demonstrate substantial equivalence to the predicate device.

1. Stability Test for single use device – NIM Essence ETT was validated to achieve 3 years shelf life for sterility and performance.
2. Sterilization Test – NIM Essence ETT is sterilized using a validated EO sterilization process which complies with ISO 11135 Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E Single batch release.
3. Biocompatibility Test – NIM Essence ETT passed all required testing under ISO 10993-1, FDA guidance “Use of international Standard ISO 10993-1” issued on September 8, 2023 and ISO 18562-1.
4. Electrical Safety Test per ANSI/AAMI ES 60601-1/IEC 60601-1 and Electromagnetic Compatibility (EMC) Test per IEC 60601-1-2 and IEC TS 60601-4-2.

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5. Performance Test (Bench) – NIM Essence ETT passed all pre-defined testing for mechanical and electrical functionality, compatibility with NIM Vital and NIM 3.0, and per ISO 5361.
6. Performance Test (Usability) – NIM Essence ETT testing has been found to be adequately safe and effective for the intended users, uses and use environments while passing compliance to IEC 62366-1 and IEC 60601-1-6.

Clinical Testing

Not applicable - No clinical study is deemed necessary since the substantial equivalence has been sufficiently demonstrated by non-clinical studies.

VIII. CONCLUSION

Based upon the supporting data summarized above, we concluded that the subject device NIM Essence™ EMG Endotracheal Tube is substantially equivalent to the legally-marketed predicate device K112686 and does not raise new or different concerns or questions of safety and effectiveness related to the predicate device. Therefore, it is the opinion of the submitter that the NIM Essence™ EMG ETT are as safe, as effective and performs as well as the legally marketing predicate device.