August 30, 2023

Medtronic Xomed, Inc.
Alexandra Oliver
Senior Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K231580
Trade/Device Name: NIM™ 35cm long Surgeon Control Probe, 1mm Ball-Tip (NIMDTP35)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: May 30, 2023
Received: May 31, 2023

Dear Alexandra Oliver:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231580

Device Name
NIM™ 35cm long Surgeon Control Probe

Indications for Use *(Describe)*
The NIM™ surgeon control probes are indicated to stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots via minimally invasive Transoral endoscopic thyroidectomy via vestibular approach - TOETVA.

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 - K231580

I. SUBMITTER

Company (submitter): Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216 USA
Telephone Number: (904) 296-9600

Date Prepared: May 19, 2023

Contact Person: Alexandra Oliver
Senior Regulatory Affairs Specialist
Telephone: (904) 332-8936
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Alexandra.j.oliver@medtronic.com

II. DEVICE

Proprietary (Trade) Name:	NIM™ 35cm long Surgeon Control Probe
Common Name:	Stimulator, nerve
Regulation Name:	Surgical nerve stimulator/locator
Regulation Number:	21 CFR 874.1820
Product Code:	ETN
Classification:	II
Panel:	77 (Ear, Nose, & Throat)

III. PREDICATE DEVICE(s)

The 35cm long NIM™ Surgeon Control Probe is substantially equivalent in intended use and technological characteristics to the following predicate device:

510(k) Number	510(k) / Device Name	510(k) Clearance Date
K213246	NIM™ Surgeon Control Probes	March 21, 2022

IV. DEVICE DESCRIPTION

Device Description

The NIM™ surgeon control probes carry stimulation current from the patient interface to the patient. It also enables the user to adjust stimulation current and key functions from the surgical site. All probes are single use devices.

Intended Use

The NIM™ surgeon control probes are intended for use as intraoperative nerve stimulators.

V. INDICATIONS FOR USE

Indications for Use

The NIM™ surgeon control probes are intended to stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots via minimally invasive Transoral endoscopic thyroidectomy via vestibular approach - TOETVA.

VI. SUBSTANTIAL EQUIVALENCE

Substantial Equivalence/Device Comparison (Subject Device(s) to Predicate Devices)

Feature/Attribute	35cm long Surgeon Control Probe (Subject Device(s))	Surgeon Control Probes, K213246 (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	Nerve Stimulator	Nerve Stimulator	SAME
Device Description	The NIM™ surgeon control probes carry stimulation current from the patient interface to the patient. It also enables the user to adjust stimulation current and key functions from the surgical site. All probes are single use devices.	The NIM™ surgeon control probes carry stimulation current from the patient interface to the patient. It also enables the user to adjust stimulation current and key functions from the surgical site. All probes are single use devices.	SAME
Intended Use	The NIM™ surgeon control probes are intended for use as intraoperative nerve stimulators	The NIM™ surgeon control probes are intended for use as intraoperative nerve stimulators	All probes are intended for the SAME use, as an intraoperative nerve stimulator.
Indications for Use	The NIM™ surgeon control probes are intended to stimulate cranial and peripheral motor nerves for location and identification during surgery, including	The NIM™ surgeon control probes are intended to stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots	The subject device's extended length is to accommodate TOETVA as a minimally invasive approach. The

Feature/Attribute	35cm long Surgeon Control Probe (Subject Device(s))	Surgeon Control Probes, K213246 (Predicate Device)	Comparison
	spinal nerve roots via minimally invasive Transoral endoscopic thyroidectomy via vestibular approach - TOETVA		usability study on the NIM 35cm long probe shows this probe length is suitable for use in a TOETVA approach.
Contraindications	The NIM™ surgeon control probes are contraindicated for use with paralyzing anesthetic agents when monitoring a motor nerve as these may reduce or eliminate the patient's EMG response.	The NIM™ surgeon control probes are contraindicated for use with paralyzing anesthetic agents when monitoring a motor nerve as these may reduce or eliminate the patient's EMG response.	SAME
Operating Principle	Electrical stimulation	Electrical stimulation	SAME
Design	Offered in a ball-tip configuration with insulated shaft and permanently molded incrementing (stim) handle for use in the sterile field	Offered in prass-tip or ball-tip configurations; both with insulated shaft and permanently molded incrementing (stim) handle for use in the sterile field	SAME
Probe tip (exposed area) tissue contact surface geometry	1mm ball	1mm ball	SAME (for ball-tip geometries respectively)
Probe working length	13.78" [35.0 cm]	3.76" [9.6cm]	The 35 cm Ball Tip probe has a longer length for extended reach. The patient contacting surfaces and stimulation performance is unaffected by this modification to the length.
Patient-contacting Materials	303 Stainless Steel with Teflon Polytetrafluoroethylene (PTFE) coating insulation	303 Stainless Steel with Xylamed coating insulation or Teflon Polytetrafluoroethylene (PTFE) coating insulation	SAME (for ball-tip materials respectively)
Patient contact	Direct	Direct	SAME
Biocompatible	Yes	Yes	SAME
Sterile	Yes	Yes	SAME
Single-Use Disposable	Yes	Yes	SAME
Duration of Use	Limited (≤24 hours)	Limited (≤24 hours)	SAME

Substantial Equivalence Discussion

A comparison of technological characteristics was provided in the submission to establish substantial equivalence. Both the subject device and the predicate device(s) share the same design,

materials, operating principle, energy source, and performance characteristics, in addition to identical intended use to stimulate cranial and peripheral motor nerves for location and identification during surgery. Furthermore, NIM™ surgeon control probes ball-tip geometry and biocompatibility mirror the predicate device(s). The subject device differs from the predicate device to accommodate TOETVA as a minimally invasive approach. The subject device probe working length is 35cm (vs 9.6cm for the predicate), and the indications for use explicitly provide for TOETVA. Usability testing performed on the 35cm long probe demonstrated that the subject device is suitable for its intended use and does not compromise the safety or performance of the subject device relative to the predicate. Therefore, the NIM™ 35cm long Surgeon Control Probe is substantially equivalent to its legally marketed predicate device.

VII. PERFORMANCE DATA

Performance Testing Discussion

Design performance testing was completed to ensure the functionality and intended use of the NIM™ 35cm long surgeon control probe was met in accordance with external standards, and device specifications via pre-defined acceptance criteria. Bench engineering test samples were subjected to simulated real-life conditions during functional testing to establish baseline data and accelerated aging data. The testing included in this submission provides objective evidence through passing results that key technological characteristics such as the ones listed below are proven to be safe and effective. This performance testing was used to support substantial equivalence, proving the subject device is as safe and effective as its predicate device.

- Electromechanical, dimensional, and visual design performance
- Sterilization validation to ISO 11135:2014
- Electrical safety & EMC testing to IEC 60601
- Biocompatibility testing and risk analysis to ISO 10993-1:2018
- Stability testing of proposed shelf life
- Packaging performance of environmental conditioning to ISTA 3A and distribution simulation to ASTM D4169
- Usability testing to IEC 62366-1:2015

VIII. CONCLUSION

Conclusion

Utilizing FDA's Guidance for Industry and Food and Drug Administration Staff, "Format for Traditional and Abbreviated 510(k)s" issued on September 13, 2019, a comparison of key performance characteristics demonstrates that the subject device, the 35cm long NIM™ Surgeon Control Probe is substantially equivalent to the predicate device(s). The 35cm long NIM™ Surgeon Control Probe has been proven to be as safe and effective as its legally marketed predicate device. The design performance testing has demonstrated that the NIM 35cm long Surgeon Control

Probe is equivalent to the predicate for delivering current for nerve stimulation. The usability study on the NIM 35cm long probe shows this probe length is suitable for use in a TOETVA approach.