March 21, 2022

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

Re: K213246
Trade/Device Name: NIM™ Surgeon Control Probes
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: February 23, 2022
Received: February 25, 2022

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213246

Device Name
NIM™ Surgeon Control Probes

Indications for Use *(Describe)*
The NIM™ Surgeon Control Probes are intended to stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

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

Date Prepared: March 15, 2022

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

II. DEVICE

Proprietary (Trade) Name: NIM™ Surgeon Control Probes
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 NIM™ Surgeon Control Probes are substantially equivalent in intended use and technological characteristics to the following predicate devices:

510(k) Number	510(k) / Device Name	510(k) Clearance Date
K873964	Nicolet Disposable Prass Probe	November 20, 1987
K992869	Xomed Monopolar Stimulator Probe	October 07, 1999

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.

VI. SUBSTANTIAL EQUIVALENCE

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

Feature/Attribute	**Surgeon Control Probes (Subject Device(s))**	**Nicolet Disposable Prass Probe / K873964 (Predicate Device)**	**Xomed Monopolar Stimulator Probe / K992869 (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
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 Prass Probes carry stimulation current from the console, via the Patient Interface, to the patient […] The incrementing prass probes provide the surgeon with the means to adjust the stimulation current at the surgical site.	The Monopolar Ball-Tip Stimulating Probes carry stimulation current from the console, via the Patient Interface, to the patient [...] The incrementing probes provide the surgeon with the means to adjust the stimulation current at the surgical site.
Intended Use	The NIM™ surgeon control probes are intended for use as intraoperative nerve stimulators	This device is intended for use as an intraoperative motor nerve stimulator with the Nerve Integrity Monitor (NIM™)	To stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots
Indications for Use	The NIM™ surgeon control probes are intended to stimulate	This device is indicated for intraoperative motor nerve monitoring	The Ball-Tip Monopolar Stimulating Probe is intended to stimulate

Feature/Attribute	Surgeon Control Probes (Subject Device(s))	Nicolet Disposable Prass Probe / K873964 (Predicate Device)	Xomed Monopolar Stimulator Probe / K992869 (Predicate Device)
	cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots		cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots
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 3.0 is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.	The NIM 3.0 is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.
Operating Principle	Electrical stimulation	Electrical stimulation	Electrical stimulation
Design	Offered in Prass-tip or Ball-tip configurations	Prass-tip configuration	Ball-tip configuration
Probe tip (exposed area) tissue contact surface geometry	• Probe Prass Tip: Flat • Probe Ball Tip: 1mm ball	Flat (Prass)	1mm ball
Probe working length	• Probe Prass: 3.76" [9.6cm] • Probe Ball: 3.76" [9.6cm]	3.76" [9.6cm]	3.76" [9.6cm]
Patient-contacting Materials	303 Stainless Steel with Xylamed coating insulation or Teflon Polytetrafluoroethylene (PTFE) coating insulation	303 Stainless Steel with Xylamed coating insulation	303 Stainless Steel with Teflon Polytetrafluoroethylene (PTFE) coating insulation
Patient contact	Direct	Direct	Direct
Biocompatible	Yes	Not available	Yes
Sterile	Yes	Yes	Yes
Single-Use Disposable	Yes	Yes	Yes
Duration of Use	Limited (≤24 hours)	Limited (≤24 hours)	Limited (≤24 hours)

Substantial Equivalence Discussion

A comparison of technological characteristics was provided in the submission to establish substantial equivalence. Both the subject device(s) and the predicate device(s) share similar characteristics (design, materials, operating principle, energy source, and performance). The similar characteristics do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

Performance Testing Discussion

Design performance testing was completed to ensure the functionality and intended use of the NIM™ Surgeon Control Probes 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(s) are as safe and effective as their predicate devices.

- 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

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(s), the NIM™ Surgeon Control Probes do not raise different questions of safety and effectiveness compared to the predicate device(s). The NIM™ Surgeon Control Probes are proven to be as safe and effective as their legally marketed predicate devices. The design performance testing has also demonstrated that the NIM™ Surgeon Control Probes perform as well as the predicates.