October 28, 2020

Medtronic Xomed, Inc.
Marek Pawlowski
Senior Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216-0980

Re: K200759
Trade/Device Name: NIM Vital, Nerve Integrity Monitor
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, ETN
Dated: September 25, 2020
Received: September 28, 2020

Dear Marek 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. 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
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200769

Device Name
NIM Vital™ Nerve Monitoring System

Indications for Use *(Describe)*

The NIM Vital™ System is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering EMG responses during surgery.

The NIM Vital™ System may be used for EMG monitoring in support of surgical procedures including: Intracranial, Extracranial, Intratemporal, Extratemporal and surgeries associated with the Neck, Spine, Thorax, and Upper and Lower Extremities.

The NIM Vital™ System is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.

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 K200759

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This Traditional 510(k) submission notifies FDA of modifications to currently marketed product - NIM™ 3.0 Nerve Integrity Monitoring Console and Patient Interface to update mechanical, electrical and software platforms due to the progress of technology.

- **Date Summary Prepared** October 28, 2020

- **Proprietary Name;** NIM Vital™ System

- **Device Name**

  Trade name: NIM Vital™, Nerve Integrity Monitor
  Common/Usual Name: Nerve Stimulator
  Classification Name: Evoked response electrical stimulator
  (21 CFR 882.1870, Product Code GWF. Class II)
  Surgical nerve stimulator/locator
  (21 CFR 874.1820, Product Code ETN, Class II
  Premarket Notification: K200759

- **Predicate Device:**
  Trade Name: NIM™ 3.0 Nerve Integrity Monitor
  Common/Usual Name: Nerve Stimulator
  Classification Name: Evoked response electrical stimulator
  (21 CFR 882.1870, Product Code GWF. Class II)
  Surgical nerve stimulator/locator
  (21 CFR 874.1820, Product Code ETN, Class II)
  Premarket Notification: K083124

- **Device Description**

The NIM Vital™ system is an electromyography (EMG) monitor for intraoperative use during surgeries in which a motor or motor-sensory nerve is at risk. The NIM Vital™ records EMG activity from the muscles innervated by the affected nerve. The system assists in early nerve identification by providing the surgeon with tools to help locate and identify the particular nerve at risk within the surgical field. The system monitors EMG activity from the muscles innervated by the nerve at risk, alerting the surgeon when a particular nerve has been activated. Nerve monitoring involves measuring and displaying amplitudes of EMG responses as well as the latency (delay) between the stimulus and the EMG response. The system also allows an option for Automatic Periodic Stimulation (APS), allowing for EMG monitoring, nerve activity trending and alerts.
This information is used throughout the procedure to determine and/or change surgical strategy in order to promote the best outcome for the patient by preserving nerve function. In addition, intraoperative monitoring can help verify the integrity of the nerve throughout the procedure.

NIM Vital™ system provides detailed intraoperative nerve condition information to inspire surgical strategy and help improve patient outcomes.
Proprietary technology notifies user in real time of nerve condition — visually and audibly.
NIM Nervassure™ continuous monitoring technology provides real-time feedback on nerve function so surgeons can adjust course, if necessary, during thyroid surgery and other procedures affecting head and neck nerves.
NIM NerveTrend™ EMG reporting enables nerve condition tracking throughout a procedure, even when using intermittent nerve monitoring.
During both continuous and intermittent trending, green, yellow and red status bars provide visual information and their associated tones provide audible cues to users of current nerve function and EMG trends.
NIM Vital™ nerve condition information can be captured in a single, meaningful snapshot.

The following components of the NIM Vital™ Nerve Integrity Monitoring System including mechanical, electrical and software design are subject of this 510(k) submission:

- **NIM Vital™ Console**
  NIM Vital™ Console controls the functions of the system:
  - Interacting with users via touch screen graphic user interface
  - Setting parameters for nerve stimulations
  - Executing stimulation procedures
  - Processing and displaying EMG responses
  - Notifying users about events by issuing audio signals
  - Interfacing with Patient Interface unit

- **NIM Vital™ Patient Interface**

Under control of NIM Vital™ Console
- Generating stimulation signals
- Receiving and processing EMG responses
- Connecting with Console wirelessly or via cable

- **NIM Vital™ Accessories:**

  - Cables allow connection between components of the system
  - Cart – provides housing for the component of the system and allows easy movement of the Console within the Operating Room
  - Adaptors – allow use of predicate NIM 3.0 System disposables with subject NIM Vital System

The NIM Vital™ System uses sterile disposables that were developed and cleared for use with the predicate device NIM™ 3.0 and are not subject of this 510(k) submission:
- Disposables:
  - Electrodes – stimulation electrodes, return electrodes, Automatic Periodic Stimulation (APS) electrodes
  - Incrementing Probes

In addition, NIM Vital™ System is using a Mute Probe – a non-sterile component of NIM™ 3.0 System to detect activation of electrocautery devices during surgical procedures.

- **Intended Use**

The NIM Vital™ system is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering electromyography (EMG) responses during surgery.

- **Indications for Use**

The NIM Vital™ System is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering EMG responses during surgery.
The NIM Vital™ System may be used for EMG monitoring in support of surgical procedures including: Intracranial, Extracranial, Intratemporal, Extratemporal and surgeries associated with the Neck, Spine, Thorax, and Upper and Lower Extremities.
The NIM Vital™ System is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.

- **Comparison of Technological Characteristics with Predicate Device**

The differences between the subject device – NIM Vital System and the predicate device NIM 3.0 System are related to updating mechanical, electrical and software platforms due to the progress of technology. These differences do not change the intended use, indications for use nor functionality of this medical device.

A summary of how the technological characteristics of the subject device NIM Vital compare to a legally marketed device NIM 3.0 is presented in Table 5.1.

Table 5.1. Summary of Characteristics

Device Name	NIM Vital (K200759)	NIM 3.0 (K083124)
Product Code	GWF, ETN	GWF, ETN
Intended Use	The NIM Vital™ system is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering electromyography (EMG) responses during surgery.	The NIM 3.0 is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal cord and spinal nerve roots. The APS electrode is an accessory intended for providing automatic periodic stimulation to nerves.
Indications for Use	The NIM Vital™ System is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering EMG responses during surgery. The NIM Vital™ System may be used for EMG monitoring in support of surgical procedures including: Intracranial, Extracranial, Intratemporal, Extratemporal and surgeries associated with the Neck, Spine, Thorax, and Upper and Lower Extremities. The NIM Vital™ System is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.	Indications for NIM EMG Monitoring Procedures include: Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities. Indications for Spinal Procedures which may use NIM 3.0 EMG monitoring include: Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery, Open and Percutaneous Lumbar and Cervical Surgical Procedures, and Thoracic Surgical Procedures.
Complies with IEC 60601-1 electrical safety standards	Yes	Yes
Console – Power supply	100V-240V +/- 10% 50/60 Hz +/- 5% Battery backup	100V-240V +/- 10% 50/60 Hz +/- 5% No battery
Patient Interface power supply	DC power from Console during wired connection, battery power in PI during wireless connection	DC power from Console
Multi-channel intraoperative neurophysiological monitor	Yes	Yes
Patient Interface	Wired / Wireless	Wired
Monitoring channels	4	4, 8
EMG parameters display	Yes	Yes
Monitoring through bipolar cautery	Yes	Yes

Device Name	NIM Vital (K200759)	NIM 3.0 (K083124)
Artifact detection software	Yes	Yes
External screen data display	Yes	Yes
Speakers	Multiple audio speakers	Single audio speaker
Continuous Intraoperative Nerve Monitoring	Yes	Yes
Event Threshold	Yes	Yes
Touch screen control	Yes	Yes
Surgeon / Procedure Setting / Customized Quick Set-up	Yes	Yes
Surgeon Incrementing Probe control	Yes	Yes
Monitoring Reports	Yes	Yes
Synchronized Electro Surgical Unit (ESU) muting	Wired using Mute Detector/ Software detection without using Mute Detector	Wired using Mute Detector
Capable of connecting various styles of patient monitoring electrodes	Yes	Yes
Capable of supplying electrical stimulus for evoked responses	Yes	Yes
Max Stim 1 Current Max Pulse Duration	50mA 1000 µS	30mA 250 µS
Max Stim 2 Current Max Pulse Duration	3mA 1000 µS	30mA 250 µS
Absolute maximum stimulation current capability	50mA	30mA
Maximum Current Density with Standard Prass Probe Contact Area = 0.204 (mm^2)	980 mA/cm^2 RMS	36.8 mA/cm^2 RMS
Actual current applied to patient at maximum stimulator setting	50mA@1000Ohms 50mA@500Ohms 50mA@250Ohms 50mA@200Ohms	30mA@1000Ohms 30mA@500Ohms 30mA@250Ohms 30mA@200Ohms
Absolute maximum energy / pulse applied to patient at maximum stimulator setting	2.5mJ@1000Ohms 1.25mJ@500Ohms 0.6mJ@250Ohms 0.5mJ@200Ohms	0.23mJ@1000Ohms 0.13mJ@500Ohms 0.06mJ@250Ohms 0.05mJ@200Ohms

Device Name	NIM Vital (K200759)	NIM 3.0 (K083124)
Lumbar, thoracic, and cervical procedures	Yes	Yes
Degenerative procedures	Yes	Yes
Pedicle screw	Yes	Yes
Neck Dissections	Yes	Yes
Orthopedic Surgery	Yes	Yes
Fusion Cages	Yes	Yes
Rhizontomy	Yes	Yes
Peripheral nerve monitoring	(Yes) Upper and lower extremities)	(Yes) Upper and lower extremities)
Accessories		
Subdermal electrode	Yes	Yes
Sterile/Single Use	Yes	Yes
Method of Sterilization	ETO	ETO
Intended for nerve stimulation	Yes	Yes
Automatic Stimulation	Yes	Yes
Intended for nerve monitoring	Yes	Yes
System with Custom Cart	Yes	Yes
Use Limited to Medtronic NIM Systems	Yes	Yes

- **Performance Characteristics**

Performance testing was performed due to the changes introduced to the device to verify that all characteristics of the predicate device are preserved in the subject device. All testing passed.

Electrical Safety Testing

Electrical Safety compliance is demonstrated through testing in accordance with:

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	Effective Date	Category
19-4	AAMI ANSI	036	ES 60601-1: 2005/I2012 and A1:2012,	C1:2009/I2012 and A2:2010/I2012 (Consolidated Text) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	07/09/2014	General II (ES/EMC)

Test results indicate that NIM Vital System complies with the applicable standards.

Electromagnetic Compatibility Testing

Electromagnetic Compatibility compliance is demonstrated through testing in accordance with:

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	FR Publication Date	Category
19-8	IEC	037	60601-1-2 Edition 4.0 2014-02	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential perfomance – Collateral standard: Electromagnetic compatibility – Requirements and tests	09/17/2018	General II (ES/EMC)

Test results indicated that NIM Vital System complies with the applicable standards.

Software Testing

Software testing was performed in compliance with the following guidance and standards:

- FDA Guidance: The content of premarket submissions for software contained in medical devices, May 11, 2005
- FDA Guidance: General principles of software validation; Final guidance for industry and FDA staff, January 11, 2002
- FDA Guidance: Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and FDA Staff, September 26, 2019
- IEC 60601-1-4 Medical Electrical Equipment, Part 1-4: Collateral Standard: Programmable Electrical Medical Systems; IEC 60601-1-4:1996 (First Ed.) + Am. 1:1999 (Consolidated 1.1 Ed.) for use with IEC 60601-1 (1988), Amts. 1 (1991) and 2 (1995)

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	FR Publication Date	Category
13-79	ANSI AAMI IEC	051	62304:2006/A1:2016	Medical device software – Software life cycle processes [Including Amendment 1 (2016)]	01/14/2019	(Software/ Informatics)

Test results indicated that NIM Vital System complies with the applicable standards.

Performance Testing – Bench

Performance testing was performed in compliance with the following standards:

FDA Recognition Number	Standard Developing Organization	Recognition List Number	Standard Designation Number and Date	Title of Standard	FR Publication Date	Category
5-89	IEC	043	60601-1-6 Edition 3.1 2013-10	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	06/27/2016	(General I (QS/RM)
5-114	AAMI ANSI IEC	046	62366-1 Edition 1.0 2015-02	Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	12/23/2016	(General I (QS/RM)
19-13	IEC	053	62133 Edition 2.0 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]	12/23/2019	General II (ES/ EMC)
19-30	AIM	050	7351731 Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers – An AIM Standard	09/17/2018	General II (ES/ EMC)
19-29	ANSI IEEE	047	C63.27-2017	American National Standard for Evaluation of Wireless Coexistence	08/21/2017	General II (ES/ EMC)
N/A	IEC 60601-2-40	N/A	IEC 60601-2-40: 2016 for use in conjunction with IEC 60601-1: 2005, CORR1:2006, CORR2:2007, AMD1:2012	Medical Electrical Equipment, Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment.	08/18/2016	N/A

Test results indicated that NIM Vital System complies with the applicable standards.

General performance verification and validation testing of the subject NIM Vital System was also performed to verify the performance and output characteristics.

The following articles were used to support safety and effectiveness of the stimulation:

- D.R. Merrill et al. / *Electrical stimulation of excitable tissue: design of efficacious and safe protocols*, Journal of Neuroscience Methods 141 (2005) 171–198
- Mark A. Castoro[a], Paul B. Yoo[a], Juan G. Hincapie[d], Jason J. Hamann[d], Stephen B. Ruble[d], Patrick D. Wolf[a], Warren M. Grill, *Excitation properties of the right cervical vagus nerve in adult dogs*, Experimental Neurology 227 (2011) 62–68
- Rick Schneider, MD; Gregory W. Randolph, MD, FACS, FACE, Gianlorenzo Dionigi, MD, FACS; et. al., *International Neural Monitoring Study Group Guideline*

2018 Part I: Staging Bilateral Thyroid Surgery With Monitoring Loss of Signal, Laryngoscope 128: October 2018, S1 - S17

- Gregory W. Randolph, MD; Henning Dralle, MD, et. Al. with the International Intraoperative Monitoring Study Group*: *Electrophysiologic Recurrent Laryngeal Nerve Monitoring During Thyroid and Parathyroid Surgery: International Standards Guideline Statement 2010,* Laryngoscope 121: January 2011, S1 - S16

In addition to testing listed above a Comparative Design Verification Test Protocol was executed to compare subject NIM Vital nerve monitoring system (wired/wireless) to the currently marketed NIM 3.0 monitoring system as evidence of monitoring equivalence of both systems.

This protocol is documenting monitoring equivalence of NIM Vital essential monitoring "User requirement elements" and "System requirement elements" as compared to the NIM 3.0 system.

Points of comparison included:

1. Electrode impedance checking
2. Monitoring active during bipolar electrocautery.
3. Wire-free synchronized Muting during Monopolar electrocautery
4. Recording Mechanical Elicited Responses
5. Recording Electrical Evoked Responses
6. APS monitoring trending and alarms

All comparison Requirements identified in the protocol have been satisfied demonstrating the Equivalency of the new NIM Vital nerve monitoring system (wired/wireless) to the currently marketed NIM 3.0 monitoring system as evidence of NIM Vital monitor equivalency to NIM 3.0 monitor.

Performance Testing - Animal

Animal testing data were not submitted with this 510(k).

Clinical Testing

Clinical testing was not submitted in this 510(k).

- **Conclusion**

NIM Vital™ Nerve Integrity Monitoring System is substantially equivalent to the predicate NIM™ 3.0 System. The updates of mechanical, electrical and software platforms have been verified and validated demonstrating that the changes meet product requirements. The changes did not affect intended use, indications for use, functionality nor fundamental technology. Further, the changes do not raise any new questions of safety and effectiveness of the Nerve Integrity Monitoring System.