December 13, 2024

Biosys Biyomedikal Muhendislik San. Ve Tic. A.S.
Cemal Erdogan
General Manager
Universiteler Mah. Ihsan Dogramaci Bul. Cd. Sk. No:23/C
Ankara, 06800
Turkey

Re: K233001
Trade/Device Name: Bioscope Neuromonitor Device
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: November 15, 2024
Received: November 15, 2024

Dear Cemal Erdogan:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233001

Device Name
Bioscope Neuromonitor Device

Indications for Use *(Describe)*

The Bioscope Neuromonitor Device is intended to help surgeons locate, identify, and preserve cranial motor nerves during surgery. Intra-operative monitoring and stimulation of cranial peripheral motor nerves.

Indications for Bioscope Neuromonitor Device Procedures include: thyroidectomy and parathyroidectomy, mastoidectomy.

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.

510(k) Summary

510(k) Submitter	Biosys Biyomedikal Mühendislik San. ve Tic. A.S.
510(k)Submitter Address	Üniversiteler Mah. İhsan Doğramaci Bul. Cd. Sk. No:23/C ÇANKAYA ANKARA
510(k) Submitter Telephone No	Phone: +90 850 800 62 97 Fax: +90 850 800 62 97
Primary Correspondent Contact Information	Cemal ERDOGAN +90 532 698 32 48 cemal.erdogan@biosys.com.tr
Summary Preparation Date	12/10/2024

Trade Or Proprietary Name	Bioscope Neuromonitor Device
Common Name	Nerve Monitor
Regulation Number	21 CFR 874.1820
Regulation Name	Surgical Nerve Stimulator/Locator
Regulatory Class	Class II
Review Panel	Ear Nose & Throat
Product Code	ETN

Subject Device Name	**Subject Device 510k No**	**Predicate Device 510k No**	**Reference Device**	**Predicate Device Manufacturer**	**Reference Device Manufacturer**
Bioscope Neuromonitor Device	**K233001**	K083242	K083124	THE MAGSTIM COMPANY LTD. SPRING GARDENS, WHITLAND CARMARTHENSHIRE, WALES, UK SA34 0HR	MEDTRONIC XOMED INC. 6743 SOUTHOINT DR. NORTH JACKSONVILLE, FL 32216

Device Description

Bioscope Neuromonitor Device is a nerve locator and monitor. The device has 3 infrastructure;

- Electronic
- Mechanic
- Software

These infrastructures are integrated with each other and work with the principle of stimulating current at 0.01-10 mA levels, conceiving EMG signals from related muscles groups. Collected signals are interpreted by the device and auditory and visual notifications will be given.

The device basically consists of stimulation and EMG subsystems. Both stimulation and EMG lines can send and collect signals from 2 channels. Depending on the operation, an EMG Endotracheal Tube or needle electrode is inserted into the muscles innervated by the relevant nerves for EMG reading. The electrode parts of the EMG tube are placed in contact with the muscles attached to the vocal cords. Needle electrodes are also inserted into the relevant muscle. Appropriate current is sent with the stimulation probe. The electrodes capture the electrical changes in the muscles in the region and are transmitted to the device as a signal. The device gives audible and visual warnings.

Channels works on the principle of potentially stimulating the critical region through monopolar or bipolar probe connection and completing the circuit, allowing the device to make a nerve-tissue separation audibly and visually. It allows the detection of nerves such as the recurrent laryngeal nerve, which are connected to the vocal cords. The doctor brings the probe into contact with the area of potential nerve risk. The current sent to the patient through the probe causes a change in the electrical activity of the nerves and the muscles to which the nerves are connected, and this change can be detected by the device. Based on the collected data, the device gives clear audible alerts for nerve-tissue separation. The EMG signal collected from the patient is displayed as a both voltage value and latency times on the output. These values can be recorded and the interface can be used to select specific details, such as the right and left sides of the thyroid or the vagus, and recurrent laryngeal nerves.

Intended Use

The Bioscope Neuromonitor Device is intended to help surgeons locate, identify, and preserve cranial motor nerves during surgery. Intra-operative monitoring and stimulation of cranial peripheral motor nerves.

Indications for Bioscope Neuromonitor Device Procedures include: thyroidectomy and parathyroidectomy, mastoidectomy.

Technological Characteristics

Criteria	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	**Bioscope Neuromonitor Device (Subject Device)**	**Neurosign Avalanche Thyroid Motor Nerve Monitor (Predicate Device)**	**Nerve Integrity monitor 3.0 (Reference Device)**	-
Owner	Biosys Biyomedikal Mühendislik San. ve Tic. A.S.	THE MAGSTIM COMPANY LTD.	Medtronic Xomed	-
510(k) No	not yet assigned	K083242	K083124	-
Product code / Class	Product Code ETN Class II	Product Code ETN Class II	Product Code ETN, G W F , Class II	Same
Description	The Bioscope neuromonitor device provides the surgeon with information through a waveform graph of EMG activity and sound amplification of this signal so that the surgeon can hear it during surgery.	Motor Nerve Monitor, based upon standard computer components, running Windows XP embedded operating system; information is provided to the surgeon via a waveform graph of EMG activity, and audio amplification of this signal so that the surgeon hears this as he/she is operating.	NIM 3.0 is a multichannel intraoperative neurophysiological monitor capable of connecting various styles of patient monitoring electrodes and supplying electrical stimulus for evoked responses.	same
Specific indication for use	Thyroidectomy, parathyroidectomy , mastoidectomy	Thyroidectomy, parathyroidectomy, mastoidectomy, cochlear implant	Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities	same
Hardware (main unit)	Embedded PCB Card	Standard PC components	unknown	Different 1
Headbox bandwidth	2 channel 100 Hz – 2 KHz	2 channel 8Hz – 8 kHz ±3dB	4/8 Channel 15 Hz – 1,85 kHZ±3dB	Different 2
Software	Embedded Software (C)	Windows XP Embedded	unknown	Different 3

Screen	10.1" colour touch screen (1024×600 pixel)	15" colour touchscreen	Touch screen, (1024×768 pixel)	Different 4
Method of control	Touchscreen – all controls via software except power ON/OFF	Touchscreen – all controls via software except power ON/OFF	Touchscreen	same
Manner of stimulator	Electrical stimulation via a probe	Electrical stimulation via a probe	Electrical stimulation via a probe	same
Stimulation range	0.01-10 mA	0.05mA – 10mA	0.01-30 mA	Different 5
Stimulation type	Constant Current (100 µs – 300 µs)	Square wave, negative edge, 200µs pulse width, constant current	Monophasic, square pulse, constant current duration 50-250 µs	Different 6
Stimulation frequency	1 Hz - 5 Hz	3 or 30Hz	1 Hz, 4 Hz, 7 Hz, 10 Hz	Different 7
Training required for use	Yes; both for surgeon and OR staff	Yes; both for surgeon and OR staff	Yes; both for surgeon and OR staff	same
Location of use	Operating room	Operating room	Operating room	same
Audio	Amplified raw EMG to provide audio (10W output)	Amplified raw EMG to provide audio (10W output)	Amplified raw EMG to provide audio	same
Display and storage	Waveform signals displayed on screen; stimulated responses may be optionally automatically recorded to disc	Waveform signals displayed on screen; stimulated responses may be optionally automatically recorded to disc	Waveform signals displayed on screen, storage on USB storage Device	same

Print capacity	Flash storage	Waveform data and patient information can be printed using the internal thermal printer or via an external Letter sized inkjet printer for the generation of reports using stored data and annotated comments	Waveform data can be printed external printer	Different 8
Power	100- 240 V 50/60 Hz	110/230V 50/60Hz	100-240 V 50/60 Hz	same
Electrical safety	EN60601-1; Type BF, Class I	EN60601-1; Type BF, Class I	EN60601-1; Type BF, Class I	same
Compliance Standards	CE Mark, EN ISO 13485, ISO 9001	CE Mark, EN ISO 13485, ISO 9001	CE Mark, EN ISO 13485, ISO 9001	same

The technological characteristics between the subject and predicate device, reference device are the same, with some exceptions given below:

Difference 1: Embedded PCB Card vs. Standard PC components

Justification: The difference in the internal components of the subject device (Embedded PCB Card) compared to the predicate device (Standard PC components) does not impact the safety or performance of the device. The subject device has been tested and passed the Low Voltage Directive (LVD) and Electromagnetic Compatibility (EMC) standards, ensuring that it complies with essential electrical safety and electromagnetic interference requirements. The use of an Embedded PCB Card may provide certain advantages, such as increased reliability and durability, which can contribute to the overall safety and performance of the device.

Different 2: Headbox bandwidth (2 channel 100 Hz-2KHz) vs. (2 channel 8Hz-8 kHZ) vs. (4,8 Channel 15 Hz – 1,85 kHZ)

Justification: Although the channel numbers of the devices (Bıoscope and Neurosign Avalanche) are the same, their bandwidths are different, but this difference is not a significant difference that will affect the operation of the device and does not create any security vulnerability or risk factor between the equivalent device and the Bioscope Neuromonitor Device. Nerve Integrity Monıtor and Bioscope have different channel counts. Reference device (Nerve Integrity Monıtor) has 4 or 8 channels. Bioscope has 2 channels. While this Nerve Integrity Monıtor device allows working in a wider diameter and area, the working range of the Bioscope device is narrower than this predicate device. This difference does not create any security vulnerability or risk factor between the equivalent device and the Bioscope Neuromonitor Device.

Difference 3: Embedded Software (C) vs. Windows XP Embedded

Justification: The difference in software architecture between the subject device (Embedded Software in C) and the predicate device (Windows XP Embedded) does not pose a significant risk to safety or performance. The subject device's software has been validated according to the EN 62304 standard, demonstrating that it meets the necessary software development and validation requirements. This ensures the reliability and safety of the software in controlling the device's functions, making it equivalent to the predicate device's software in terms of safety and performance.

Difference 4: 10.1” Color Touch Screen vs. 15” Color Touchscreen

Justification: The difference in screen size between the subject device (10.1" color touchscreen) and the predicate device (15" color touchscreen) is unlikely to affect safety or performance. The subject device's 10.1" color touchscreen is legible and provides sufficient interface for users to operate the device effectively. The primary purpose of the touchscreen is to display information and allow user interaction, and the smaller size does not compromise the device's core functionality, safety, or performance.

Different 5: Stimulation Range (0.01-10 mA) and (0.01 mA – 30 mA)

Justification: The subject device (0.01-10 mA) and predicate device (0.01 mA – 10 mA) stimulation ranges are the same. The reference device stimulation range (0.01 mA – 30 mA) is different from the subject device and predicate device. The reference device has a wider stimulation range. The current ranges of devices produced as nerve monitors may vary. The current range of the subject device is sufficient for the operations in which the device will be used.

Different 6: Stimulation type Constant Current 100 µs – 300 µs and Constant Current 200 µs pulse width - Constant Current 50 - 250 µs

Justification: There are differences between the stimulation types of devices. While the Bioscope Neuromonitor Device is in the Constant Current (100 µs – 300 µs) range, Neurosign Avalanche is in the constant current (200 µs pulse width) range and Nerve Integrıty Monıtor is in the constant current (50-250 µs pulse width) range. This difference does not create a significant difference between devices and does not pose a risk. Devices operate with constant current, and the operating value of the equivalent devices is within the operating range of the Bioscope Neuromonitor device.

Difference 7: Stimulation Frequency (1 Hz - 5 Hz) vs. (3 Hz or 30 Hz) vs. (1 Hz, 4 Hz, 7 Hz, 10 Hz)

Justification: The difference in stimulation frequency between the subject device (1 Hz - 5 Hz) and the predicate device Neurosign Avalanche is (3 Hz or 30 Hz) and reference device Nerve Integrıty Monıtor is (1 Hz, 4 Hz, 7 Hz, 10 Hz)) does not pose a significant safety or performance concern. The frequency range of the subject device is between the ranges of predicate device and reference device. The frequency range of the subject device is between the ranges of predicate device and reference device. The subject device's broader frequency range (1 Hz - 5 Hz) offers flexibility and compatibility with a wider range of clinical scenarios without compromising safety.

Difference 8: Flash Storage Print Capacity vs. Thermal Printer and External Printer

Justification: The difference in data printing methods between the subject device (flash storage print capacity) and the predicate device (thermal printer and external printer) does not impact safety or performance. The subject device is capable of printing waveform data and patient information using flash storage, ensuring that data can be accurately documented and reported. This approach offers an alternative and equally effective method for generating reports and preserving data integrity without loss, equivalent to the predicate device's printing capabilities.

The Bioscope Neuromonitor device has similar technical features to predicate device and reference device. Performance testing has been conducted to support the safety and effectiveness of the Bioscope Device. This 510(k) submission demonstrates that the similarities and common features between the Bioscope and predicate device and reference device do not raise any questions about its safety and effectiveness. The Bioscope Neuromonitor, as designed and manufactured, is as safe and effective as the predicate device and reference device therefore, has been determined to be substantially equivalent to the referenced predicate device. In summary, the identified differences between the subject device and the predicate device do not pose significant risks to safety or performance. Additionally, it meets essential electrical safety and regulatory standards.

Non-Clinical Performance Testing

The Bioscope Neuromonitor Device is subject to the following standards and requirements are met. Test results demonstrate that the Bioscope Neuromonitor Device complies with the applicable standards.

Recognition number	Standard Designation Number and Date	Title of Standard
19-49	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
19-36	ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
5-132	ANSI AAMI IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13-79	ANSI AAMI IEC 62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

19-34	ANSI AANI IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	Safety requirements for electrical equipment for measurement control and laboratory use- Part 1: General requirements
17-16	IEC 60601-2-10 Edition 2.1 2016-04	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
5-131	IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

In addition, the following performance tests were performed to test and prove the performance of the device:

- Software verification and validity test;
- Usability test;
- Electrical safety and electromagnetic compatibility (EMC) test;
- Low Voltage Directive Test (LVD);
- System Performance test - (All basic functions of the device were tested: Device opening, closing, parameter change, accuracy of the current coming out of the device, accuracy of the signal detected by the device, compatibility of the device with consumables.)

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as the legally marketed predicate device.