April 1, 2021

Magstim Company Ltd.
Tom Campbell
Chief Quality & Regulatory Affairs Officer
Spring Gardens
Whitland, Carmarthenshire SA34 0HR
United Kingdom

Re: K203684
Trade/Device Name: Neurosign V4 Intraoperative Nerve Monitor
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: PDQ

Dear Tom Campbell:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 17, 2021. Specifically, FDA is updating this SE Letter due to typographical errors in the Indications for Use Statement as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jay Gupta, OHT5: Office of Neurological and Physical Medicine Devices, Jay Gupta, 301-796-2795, jay.gupta@fda.hhs.gov.

Sincerely,

Jay R. Gupta -S

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

March 17, 2021

Magstim Company Ltd.
Tom Campbell
Chief Quality & Regulatory Affairs Officer
Spring Gardens
Whitland, Carmarthenshire SA34 0HR
United Kingdom

Re: K203684
Trade/Device Name: Neurosign V4 Intraoperative Nerve Monitor
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: December 17, 2020
Received: December 17, 2020

Dear Tom Campbell:

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,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
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and Physical Medicine Devices
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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)*
K203684

Device Name
Neurosign® V4 Intraoperative Nerve Monitor

Indications for Use *(Describe)*
The Neurosign® V4 Intraoperative Nerve Monitor is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal nerve roots.

Indications for Neurosign® V4 EMG Monitoring Procedures include: Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities.

Indications for spinal procedures which may use Neurosign® V4 EMG monitoring include: Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery and Open and Percutaneous Lumbar Procedures.

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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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."

K203684
Traditional 510(k) SUMMARY
Magstim's Neurosign® V4 Intraoperative Nerve Monitor

Prepared according to the requirements outlined in 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Magstim Company Limited
Spring Gardens, Whitland, Carmarthenshire
SA34 OHR, United Kingdom

Phone: +44 (0) 1994 240798
Facsimile: +44 (0) 1994 240061

Contact Person: Tom Campbell, Chief Quality & Regulatory Affairs Officer
regulatory@magstim.com

Date Prepared: March 17, 2021

Trade Name of Device

Neurosign® V4 Intraoperative Nerve Monitor

Common or Usual Name

Neurosurgical Nerve Locator

Classification

Neurosurgical Nerve Locator

21 CFR 874.1820, Class II, product code PDQ

Predicate Devices

K181559 Neurosign® V4 Intraoperative Nerve Monitor, The Magstim Company Limited *(Primary Predicate Device)*, 21 CFR 874.1820, PDQ, ETN

K053141 Neurosign® Nerve Monitor, Model Neurosign® 400 and Neurosign® 800, The Magstim Company Limited *(Secondary Predicate)*, 21 CFR 874.1820, ETN

Device Description

The Neurosign® V4 Intraoperative Nerve Monitor (IONM) is a multi-channel nerve monitor designed for use in Ear, Nose and Throat (ENT) surgery and neurosurgery. The subject device differs from its primary predicate due to the introduction of improved Pre-amplifier and Stimulator pod cables, as well the addition of an 8-channel Pre-amplifier variant.

Using needle or surface electrodes[1] connected to the Pre-amplifier, the nerve monitor detects electromyographic (EMG) signals within muscles caused by the contraction of the muscle due to mechanical manipulation or electrical stimulation of the nerve controlling it. The Neurosign® V4 then amplifies the EMG data into an audible signal and displays the data as a waveform on the active monitoring screen.

The Neurosign® V4 Intraoperative Nerve Monitor is used for patient treatment by prescription only under the supervision of a licensed physician.

The Neurosign® V4 is an integrated system consisting of a combination of hardware, software, and accessories. Its technological characteristics are described in further detail below.

Intended Use

The Neurosign® V4 Intraoperative Nerve Monitor is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal nerve roots.

Technological Characteristics

The Neurosign® V4 is comprised of following components:

1. Neurosign® V4 Intraoperative Nerve Monitor
2. Neurosign® V4 Pre-amplifier:
    a. Neurosign® V4 Pre-amplifier – 4-Channel
    b. Neurosign® V4 Pre-amplifier – 8-Channel
3. Neurosign® V4 Stimulator Pod
4. Neurosign® V4 Mute Sensor

The Neurosign® V4 Intraoperative Nerve Monitor (IONM) includes a user interface comprised of an audio output, a color graphics display with a touch screen and dedicated rotary controls for frequently adjusted parameters.

EMG signals are collected from the patient using needle and surface electrodes [1] connected to the Neurosign® V4 Pre-amplifier. The pre-amplifier is available in a 4-channel or 8-channel variant, allowing the user to monitor up to eight separate neural pathways depending on the pre-amplifier used. The Neurosign® V4 Pre-amplifier collects, processes and transmits the EMG signals to the IONM for display and for an audio output.

The Neurosign® V4 Stimulator Pod allows the simultaneous connection of two stimulating probes[2] for the mapping and locating of nerves within tissue, and to test the nerve activity at various stages during surgery.

Software documentation for a “major” level of concern has been provided.

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[1] *Single use electrodes and probes not subject to this submission*

[2] *Single use electrodes and probes not subject to this submission*

Non-Clinical Testing

Table 1: Summary of Non-Clinical Testing

Test	Method	Results/ Comment
Electrical Safety Mechanical Safety	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012– Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; FDA Recognition Number: 19-4	A sample Neurosign® V4 (4-Channel and 8-Channel Variants) has been tested and found to be compliant to the requirements of IEC 60601-1 by independent test laboratory Element Materials Technology, to demonstrate safety and effectiveness of the system following incorporation of new/ different characteristics as compared to the predicate device.
		Following the design changes to the Pre-amplifier and Stimulator Pod cables, non-clinical bench testing was performed by Magstim confirming that there is no discernable difference in the isolation parameters of the new cable design in comparison to the old.
Electromagnetic Compatibility	IEC 60601-1-2: 2014 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests; FDA recognition number: 19-8	A sample Neurosign® V4 (4-Channel) has been tested and found to be compliant to the requirements of EN 60601-1-2 by independent test laboratory Eurofins Hursley, to demonstrate safety and effectiveness of the system following incorporation of new/ different characteristics as compared to the predicate device.
		Following the design change to the Pre-amplifier and Stimulator Pod cables, non-clinical bench testing was performed by Magstim concluding there is no discernable difference in the EMC performance of the new cable design in comparison to the old.
Alarm Systems	IEC 60601-1-8 – 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; FDA Recognition Number: 5-76	A sample Neurosign® V4 has been tested and found to be compliant to the requirements of IEC 60601-1-8 by independent test laboratory Element Materials Technology, thus demonstrating the Neurosign® V4 is substantially equivalent to the legally marketed predicate device.
Biocompatibility	ISO 10993-1:2009 - Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process	The Neurosign®V4 Nerve Monitor is not intended to come into contact with the patient, as patient contact is achieved

	ISO 10993-5:2009 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; FDA Recognition Number: 2-245	via use of single use electrodes and probes. However, the Stimulator Pod, Pre-amplifier and connecting leads may come into contact with the patient. Samples of these materials have been tested and found to be compliant to the requirements of ISO 10993-1, ISO 10993-5 and ISO 10993-10 by an independent test laboratory, thus demonstrating the Neurosign® V4 is substantially equivalent to the legally marketed predicate device.
	ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization; FDA Recognition Number: 2-174	
Human Factors Testing	AAMI/ANSI HE75 - Human Factors Engineering – Design of Medical Devices; FDA Recognition Number: 5-57	Usability testing was performed to analyze the user experience of the 8-Channel Neurosign® V4. The Human Factors Engineering report verifies the Neurosign V4, using the 8-channel pre-amplifier, to be safe and effective for the intended users, uses, and use environments thus demonstrating the Neurosign® V4 is substantially equivalent to the legally marketed predicate device.
	IEC 62366-1 - Medical Devices - Part 1: Application of Usability Engineering To Medical Devices; FDA Recognition Number: 5-114	

The software verification and validation testing further demonstrated that the software performs as intended and in accordance with specifications. In accordance with ISO14971, risks associated with the Neurosign® V4 have been identified, assessed and, where necessary, mitigated with risk control measures to an acceptable level.

Substantial Equivalence Discussion

The Neurosign® V4 (subject of this submission) is substantially equivalent to the primary predicate device, the Neurosign® V4 Intraoperative Nerve Monitor (K181559) and the secondary predicate device, the Neurosign® Nerve Monitor Model Neurosign® 400 and Model Neurosign® 800® (K053141).

The intended use and indications for use are identical between the Neurosign® V4 (subject of this submission) and the primary predicate device, the Neurosign® V4 Intraoperative Nerve Monitor (K181559).

All devices have the same four principal components:

(1) Intraoperative Nerve Monitor,
(2) Pre-amplifier,
(3) Stimulator and
(4) Mute Sensor.

The notable difference between the subject device Neurosign® V4 and that which was cleared earlier in K181559 includes the redesign of the Pre-amplifier and Stimulator pod

cables to improve reliability and malleability during use, as well the addition of an 8-channel Pre-amplifier variant, enabling the user to monitor up to eight separate neural pathways at risk during surgery. The Neurosign® V4 8-Channel Pre-amplifier is substantially equivalent to the Neurosign® V4 4-Channel Pre-amplifier previously cleared under K181559, with the addition of 4 additional electrode channels.

Furthermore, the addition of an 8-channel Pre-amplifier is supported by the clearance of the secondary predicate device (K053141), as the secondary predicate includes the option to monitor up to eight separate neural pathways at risk during surgery.

The Principles of Operation are identical to the primary predicate device, the Neurosign® V4 Intraoperative Nerve Monitor (K181559). Both the subject device and the predicate device systems are all systems that are intended for use in collecting, processing and representing EMG signals from nerves at of choice during surgery.

Both the subject and predicate devices use a stimulator for the mapping and locating of nerves within tissue and testing the nerve activity at various stages during surgery. All offer the option to use a mute sensor to silence the audio output during episodes of RF interference from electrocautery.

A summary of the similarities and minor differences between the Neurosign® V4, the previous Neurosign® V4 *(primary predicate device)* and the Neurosign® Nerve Monitor Model Neurosign® 400 and Model Neurosign® 800 *(Secondary Predicate Device)* are described in **Table 2.**

Conclusions

In summary, the subject and predicate devices are substantially equivalent based on their identical intended use and similar technological characteristics, which have been tested according to the applicable non-clinical performance testing.

Non-clinical test data demonstrates that the Neurosign® V4 is as safe and effective as the predicate devices.

Thus, the Neurosign® V4 Intraoperative Nerve Monitor is substantially equivalent to the primary predicate device, the Neurosign® V4 Intraoperative Nerve Monitor (K181559), and the secondary predicate device, the Neurosign® Nerve Monitor, Model Neurosign® 400.

Table 2: Substantial Equivalence Summary

Criteria of Comparison	**K203684** Neurosign® V4 Intraoperative Nerve Monitor (*Subject of this submission*)	**K181559** Neurosign® V4 Intraoperative Nerve Monitor *(Primary Predicate Device)*	**K053141** Neurosign® Nerve Monitor, Model Neurosign® 400 and Model Neurosign® 800® *(Secondary Predicate Device)*
Manufacturer	Magstim Company Limited	Magstim Company Limited	Magstim Company Limited
Device Name	Neurosign® V4 Intraoperative Nerve Monitor	Neurosign® V4 Intraoperative Nerve Monitor	Neurosign® Nerve Monitor, Model Neurosign® 400
Product code(s) & regulation	PDQ 21 CFR 874.1820	PDQ, ETN 21 CFR 874.1820	ETN 21 CFR 874.1820
Intended Use/ Indications for Use	The Neurosign® V4 Intraoperative Nerve Monitor is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal nerve roots. Indications for Neurosign® V4 EMG Monitoring Procedures include: Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities. Indications for spinal procedures which may use Neurosign® V4 EMG monitoring include: Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery and Open and Percutaneous Lumbar Procedures.	The Neurosign® V4 Intraoperative Nerve Monitor is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal nerve roots. Indications for Neurosign® V4 EMG Monitoring Procedures include: Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities. Indications for spinal procedures which may use Neurosign® V4 EMG monitoring include: Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery and Open and Percutaneous Lumbar Procedures.	To locate and identify cranial motor nerves during ENT and intra-cranial procedures.
	Intraoperative Nerve Monitor		
Type of monitor	EMG	EMG	EMG
System hardware	Digital	Digital	Digital
Display	15” color touchscreen	15” color touchscreen	125mm x 95mm electroluminescent display

Criteria of Comparison	**K203684** Neurosign® V4 Intraoperative Nerve Monitor (*Subject of this submission*)	**K181559** Neurosign® V4 Intraoperative Nerve Monitor *(Primary Predicate Device)*	**K053141** Neurosign® Nerve Monitor, Model Neurosign® 400 and Model Neurosign® 800® *(Secondary Predicate Device)*
Stimulator adjust	By control knob	By control knob	By control knob
Volume adjust	By control knob; individual channels by touchscreen	By control knob; individual channels by touchscreen	By control knob
Needle placement impedance checking	Yes	Yes	No
	Amplifier		
Number of channels	4 (4-Channel Pre-amplifier) 8 (8-Channel Pre-amplifier)	4	4 (Neurosign® 400) 8 (Neurosign® 800)
Color coded electrode sockets	Yes	Yes	Yes
Bandwidth	10Hz – 1kHz	10Hz – 1kHz	10Hz – 5kHz
Common mode rejection ratio	> 90dB @ 50/60Hz	> 90dB @ 50/60Hz	> 95dB @ 50/60Hz
	Stimulator		
Stimulator channels	Channel 1: 2 probes	Channel 1: 2 probes	Channel 1: 2 probes
Operational mode	Constant Current or Constant Voltage	Constant Current or Constant Voltage	Constant Current or Constant Voltage
Current ranges	10µA – 10mA	10µA – 10mA	50µA – 10mA
Voltage ranges	10mV – 10V	10mV – 10V	50mV – 10V
Accuracy	<u>Current Stimulating Mode</u> ± 10% (1mA – 10mA), into 1kΩ load ± 25% (10µA - 990 µA), into 1kΩ load <u>Voltage Stimulating Mode</u> ± 10% (1V – 10V), into 1kΩ load ± 25% (10mV - 990 mV), into 1kΩ load	<u>Current Stimulating Mode</u> ± 10% (1mA – 10mA), into 1kΩ load ± 25% (10µA - 990 µA), into 1kΩ load <u>Voltage Stimulating Mode</u> ± 10% (1V – 10V), into 1kΩ load ± 25% (10mV - 990 mV), into 1kΩ load	<u>Current Stimulating Mode</u> ± 10% (50µA - 10mA), into 1kΩ load <u>Voltage Stimulating Mode</u> ± 10% (50mV – 10V), into 1kΩ load
	Mute Sensor		
Available	Yes	Yes	Yes
	Operational Environment		

Criteria of Comparison	**K203684** Neurosign® V4 Intraoperative Nerve Monitor (*Subject of this submission*)	**K181559** Neurosign® V4 Intraoperative Nerve Monitor *(Primary Predicate Device)*	**K053141** Neurosign® Nerve Monitor, Model Neurosign® 400 and Model Neurosign® 800® *(Secondary Predicate Device)*
Operating temperature	5°C to 40°C	5°C to 40°C	5°C to 30°C
Relative humidity	10% to 80% (non-condensing)	10% to 80% (non-condensing)	30% to 70% (non-condensing)
Atmospheric pressure	70kPa to 106kPa	70kPa to 106kPa	50kPa to 106kPa