November 9, 2018

Magstim Company Ltd.
Tom Campbell
Regulatory Affairs Manager
Spring Gardens
Whitland, SA34 0HR Gb

Re: K181559
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: October 8, 2018
Received: October 10, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K181559

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

## 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

Date Prepared: October 5, 2018

## Name of Device

Neurosign® V4 Intraoperative Nerve Monitor

## Common or Usual Name/

Surgical Nerve Stimulator / Locator

## Classification

Surgical Nerve Stimulator / Locator

21 C.F.R. § 874.1820, Class II, product code PDQ

## Predicate Devices

NIM 3.0, MEDTRONIC XOMED, INC. (K083124) *(Primary Predicate Device)*
Neurosign® Nerve Monitor, Model Neurosign® 400, The Magstim Company Limited (K053141) *(Secondary Predicate Device)*

## Device Description

The Neurosign® V4 Intraoperative Nerve Monitor is a multi-channel nerve monitor designed for use in Ear, Nose and Throat (ENT) surgery and neurosurgery.

Using needle or surface electrodes [1] connected to the Pre-Amplifier Pod, 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.

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

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.

**Indications for Use**

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.

**Technological Characteristics**

The Neurosign® V4 is comprised of following four components:

1. Neurosign® V4 Intraoperative Nerve Monitor
2. Neurosign® V4 Pre-Amplifier Pod – 4 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]. The Neurosign® V4 Pre-Amplifier Pod 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 [1] 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*

## Non-Clinical Testing

### Table 1: Summary of Non-Clinical Testing

| Test | Test Method Summary | Results |
|---|---|---|
| Electrical Safety<br>Mechanical Safety | IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012 –<br>Medical electrical equipment – Part 1: General requirements for<br>basic safety and essential performance | A sample Neurosign® V4 has been tested and found to be compliant to the requirements of IEC 60601-1 by independent test laboratory Element Materials Technology, , thus demonstrating the Neurosign® V4 is substantially equivalent to the legally marketed predicate device. |
| Electromagnetic Compatibility | EN 60601-1-2: 2007 –<br>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -<br>Collateral standard: Electromagnetic compatibility -Requirements and tests | A sample Neurosign® V4 has been tested and found to be compliant to the requirements of EN 60601-1-2 by independent test laboratory Kiwa Blackwood Compliance Laboratories, thus demonstrating the Neurosign® V4 is substantially equivalent to the legally marketed predicate device.<br>EN 60601-1-2 (2007) is equivalent to the FDA recognized standard IEC 60601-1-2. A justification of this assertion is provided in **Appendix 06**. |
| Alarm Systems | IEC 60601-1-8 –<br>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 | 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 via use of single use electrodes and probes.<br>However, the Stimulator Pod, Pre-Amplifier Pod and connecting leads may come into contact with the patient.<br>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 independent test laboratories Harlan Laboratories Ltd and Envigo Research Ltd, thus demonstrating the Neurosign® V4 is substantially equivalent to the legally marketed predicate device. |
| | ISO 10993-5:2009 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity | |
| | ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | |

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|---|---|---|
| Amplifier - EMG Acquisition & EMG Display Equivalence Testing | Using a function generator, a range of input voltages at a set frequency were applied to both the Neurosign® V4 and NIM-Response 3.0 to replicate an EMG signal. | Testing demonstrated that the measured EMG responses on the Neurosign® V4 and the NIM-Response 3.0 are within 5% of the target input and ±1% of each other, thus demonstrating the Neurosign® V4 is substantially equivalent and performs as well as than the legally marketed predicate device. |
| Stimulator Equivalence Testing | A 1kΩ Resistor was connected across the stimulator output terminals and the oscilloscope was used to measure the potential difference across the resistor. A range of input currents were used to compare the output waveforms and show the relative amplitude. | Testing demonstrated that the Neurosign® V4 and the NIM-Response 3.0 have almost identical stimulator performance, thus demonstrating the Neurosign® V4 is substantially equivalent and performs as well as than the legally marketed predicate device. |
| | 1kΩ Resistor was connected across the stimulator output terminals and the oscilloscope was used to measure the stimulator pulse width. A range of pulse width settings were chosen as they are representative of typical use. | Testing demonstrated that the Neurosign® V4 and the NIM-Response 3.0 have almost identical stimulator pulse width performance, thus demonstrating the Neurosign® V4 is substantially equivalent and performs as well as than the legally marketed predicate device. |

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**

The Neurosign® V4 is substantially equivalent to the predicate device, the NIM 3.0 (K083124).

The intended use and indications for use of the Neurosign® V4 is a subset of the primary predicate device, the NIM 3.0 (K083124). The difference includes the omission of '*Spinal Cord*' and reference to the '*APS Electrode*' in the intended use and '*Cervical Surgical Procedures, and Thoracic Surgical Procedures*' in the indications for use. A discussion on this omission is given in **Section XIV.**

The technological characteristics are equivalent. All devices have the same four principle components: (1) Intraoperative Nerve Monitor, (2) Amplifier, (3) Stimulator and (4) Mute Sensor.

The principals of operation of the Neurosign® V4 is equivalent to the primary predicate device, the NIM 3.0 (K083124) and the secondary predicate device Neurosign® Nerve Monitor, Model Neurosign® 400 (K053141) as all systems are based on collecting, processing and representing EMG signals from nerves at risk during surgery. All devices use a stimulator for the mapping and locating of nerves within tissue, and to test 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.

The Neurosign V4® meets the same electrical and mechanical safety standards (IEC 60601-1) and the same EMC standards (EN 60601-1-2).

The similarities and minor differences between the Neurosign® V4, the NIM 3.0 *(primary predicate device)* and the Neurosign® Nerve Monitor, Model Neurosign® 400 *(Secondary Predicate Device)* are described in **Table 2.**

## Conclusions

In summary, the intended use and indications for use of the Neurosign® V4 is a subset of the primary predicate device, the NIM 3.0 (K083124).

Furthermore, the Neurosign® V4 has equivalent technological characteristics and equivalent principles of operation compared to the predicate devices.

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 NIM 3.0 (K083124) and the secondary predicate device the Neurosign® Nerve Monitor, Model Neurosign® 400 (K053141).