K083242
1 of 5

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The product information is as follows:

Neurosign Avalanche Motor Nerve Monitor

Product:	Neurosign Avalanche
Class:	Class CFR 874.1820
Panel:	Ear, Nose and Throat
Product Code:	ETN

Classification name:	Surgical Nerve Stimulator/Locator
Common or usual names:	Nerve Monitor
Proprietary name:	Neurosign Avalanche Motor Nerve Monitor

K083242
2 of 5

5.1 Description of the Devices

The Neurosign Avalanche Motor Nerve Monitor is a 2 or 4 channel nerve monitor for intraoperative use in general surgery, skull-base surgery and ENT. The Neurosign Avalanche Motor Nerve Monitor allows the user to detect motor nerves and to check their integrity by acquiring the compound muscle action potentials at the target muscles. The acquired signals are processed by the monitor and displayed as waveforms on the monitor screen and played back acoustically via the built in audio amplifier and loudspeaker.

The Neurosign Avalanche Motor Nerve Monitor provides additional information to the user, helping the surgeon to locate nerves by using an electrical stimulator. The sound is independent from the waveform display on the monitor's screen.

The displayed waveforms can be printed along with the patient information via the built in thermal array printer, or as a generated report in Word format.

5.2 Intended Use of the Devices

The Neurosign Avalanche Motor Nerve Monitor is intended to help surgeons locate, identify, and preserve cranial motor nerves during surgery.

The intended uses of the Neurosign Avalanche Motor Nerve Monitor are:

2 channel	thyroidectomy and parathyroidectomy, mastoidectomy
4 channel	parotidectomy, mastoidectomy, skull-base

5.3 Predicate Devices

The predicate device used in this submission is:

- Neurosign® 400 Motor Nerve Monitor (reference K991583).

5.3.1 Comparison with the predicate device

K083242
3 of 5

	Neurosign Avalanche Thyroid Motor Nerve Monitor (Subject Device)	Neurosign Avalanche EMG Motor Nerve Monitor (Subject Device)	Neurosign 400 Motor Nerve Monitor (Predicate Device)
Description	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	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	Motor Nerve Monitor, based upon proprietary hardware and software; 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
Intended Use	Intra-operative monitoring and stimulation of peripheral motor nerves	Intra-operative monitoring and stimulation of cranial and peripheral motor nerves	Intra-operative monitoring and stimulation of cranial and peripheral motor nerves
Specific Indications For Use	Thyroidectomy, parathyroidectomy, mastoidectomy, cochlear implant	Thyroidectomy, parathyroidectomy, mastoidectomy, parotidectomy, cochlear implant, acoustic neuroma, facial nerve neuroma, meningioma	Mastoidectomy, parotidectomy, skull-base
Hardware (main unit)	Standard PC components	Standard PC components	Proprietary microprocessor design
Headbox Bandwidth Signal Gain	2 channel 8Hz – 8kHz ±3dB 500	4 channel 8Hz – 8kHz ±3dB 500	4 channel 10Hz – 5kHz ±3dB 477
Software	Windows XP Embedded	Windows XP Embedded	C++ proprietary code
Screen	15" colour touchscreen	15" colour touchscreen	6" electroluminescent display
Method of control	Touchscreen – all controls via software except power ON/OFF	Touchscreen – all controls via software except power ON/OFF	Controls via dedicated buttons or via software using menus selected using front-panel buttons
Manner of Stimulation	Electrical stimulation via a probe	Electrical stimulation via a probe	Electrical stimulation via a probe
Stimulation Range	0.05mA - 10mA	0.05mA - 10mA	0.05mA - 5mA
Stimulation Type	Square wave, negative edge, 200µs pulse width, constant current	Square wave, negative edge, 200µs pulse width, constant current	Square wave, negative edge, default 200µs pulse width, selectable from 100 to 500µs, constant current, constant voltage

K063242
4 of 5

Stimulation Frequency	3 or 30Hz	3 or 30Hz	3 or 30 Hz
Stimulation Probes	Monopolar, bipolar, concentric	Monopolar, bipolar, concentric	Monopolar, bipolar, concentric
Electrodes	Laryngeal electrode; needle electrodes	Laryngeal electrode; needle electrodes	Laryngeal electrode; needle electrodes
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
Location of Use	Operating Room	Operating Room	Operating Room
Audio	Amplified raw EMG to provide audio (10W output)	Amplified raw EMG to provide audio (10W output)	Amplified raw EMG to provide audio (14W output)
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; individual screens may be stored in non-volatile memory
Print Capacity	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 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 to a proprietary external thermal printer
Power	110/230V 50/60Hz	110/230V 50/60Hz	110/230V 50/60Hz
Electrical Safety	EN60601-1; Type BF, Class IIA	EN60601-1; Type BF, Class IIA	UL260601-1; Type BF, Class I
Compliance Standrads	CE Mark; EN ISO 13485	CE Mark; EN ISO 13485	CE Mark; BS EN 9001; EN ISO13485

5.4 Non-Clinical Tests Undertaken

The Neurosign 400 and the Neurosign Avalanche XT Thyroid and EMG nerve monitors were assessed in a non-clinical setting and were determined to be similar in the following areas:

K083242
5 of 5

Feature	Neurosign 400	Neurosign Avalanche	Comments
Intended use	Cranial motor nerve monitoring	Cranial motor nerve monitoring	All the machines are intended for the same purpose, with the Thyroid version restricted to simpler applications
Method of operation	EMG monitor and stimulator	EMG monitor and stimulator	All machines detect EMG and amplify it so it is audible to the surgeon, as well as displaying the EMG in a graphical format
Stimulation frequency	3 or 30Hz	3 or 30Hz	All machines use the same frequencies, pulse width and rectangular waveform
Method of display	Display shows amplitude triggered response for continuous monitoring, and switches to stimulator triggered response when using the stimulator	Screen is divided into 2 sections, 1 showing amplitude triggered responses in real time, the other showing stimulator triggered responses	The information displayed is the same, but presented in different manner
Audio	14W rms amplifier	10W rms amplifier	All machines amplify the EMG signal to generate an audible response. The sound is simply amplified and is proportional to the input signal. It is intended to interact directly with the surgeon
Signal detection	Needle and Laryngeal electrode	Needle and Laryngeal electrode	The same electrodes and stimulating probes are used

Based upon these criteria, it was considered that the Neurosign 400 was a suitable predicate device for the Neurosign Avalanche XT Thyroid and XT EMG monitors.

5.5 Conclusions

The Neurosign Avalanche Motor Nerve Monitor is both safe and effective and is similar in its risks and benefits, as well as its manner of performance, to the predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Magstim Company Limited
c/o Anwen Evans
Regulatory Affairs Manager
Spring Gardens, Whitland
Carmarthenshire, Wales, UK
SA34 OHR

JUL 2 9 2009

Re: K083242
Trade/Device Name: Neurosign® Avalanche Motor Nerve Monitor
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: ETN
Dated: July 9, 2009
Received: July 14, 2009

Dear Ms. Evans:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 083242

Device Name: Neurosign® Avalanche Motor Nerve Monitor

Indications for Use:

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The intended uses of the Neurosign Avalanche Motor Nerve Monitor is:

2 channel	thyroidectomy and parathyroidectomy, mastoidectomy
4 channel	parotidectomy, mastoidectomy, skull-base

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K083242