K071349

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SECTION 5: 510(k) SUMMARY

DEC 1 2 2007

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850
04 May 2007

Contact information:

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The product information is as follows:

Product: Laryngeal Electrode for use with the Neurosign® 100, 400 and 800 nerve monitors
Class: Class II CFR §874.1820 Surgical Nerve Stimulator and Locator
Panel: Ear, Nose and Throat
Product Code: ETN

Classification name: Nerve Stimulator (Class II)
Common or usual names: Laryngeal Electrode
Proprietary name: Neurosign® Laryngeal Electrode

5.1 Description of the Device

The Neurosign® Laryngeal Electrode, which was specially developed for use with the Neurosign® 100, 400 and 800 models, consists of: a single-use electrode constructed from medical-grade inks suspended in a polyester substrate; a connector made of polypropylene; and a cable assembly. The electrode is available in two sizes to suit different sexes and age groups. The 6/7mm electrode should be used with a 6 or 7mm endotracheal tube; the 8/9mm electrode should be used with an 8 or 9mm tube. The cable assembly is available separately and will have a long life if it is not abused and is stored appropriately.

Using the laryngeal electrode lowers the risk of damage to the laryngeal or Xth cranial nerve (the Vagus nerve) during thyroidectomy or parathyroidectomy and, since it is non-invasive, it also lessens the risk of infection during the monitoring procedure.

5.2 Intended Use of the Device

The non-invasive Laryngeal Electrode is intended for use as an intraoperative method of monitoring the laryngeal nerves during thyroid surgery, and of the Xth cranial nerve during skull-base surgery. The monitoring is performed by a surface electrode held in position against the vocal cords through an attachment to a normal endotracheal tube. The electrode is then connected to a Neurosign® machine for readout. A connector allows the cable to connect with the Neurosign® Nerve Monitor Pre-Amplifier Pod. The electrode detects EMG in the vocalis or the posterior cricoarytenoid muscles and will also detect stimulation of the superior laryngeal nerves during radical neck dissections.

The Neurosign® Laryngeal Electrode is indicated for use when it is necessary to continuously monitor the laryngeal nerves, the Xth cranial nerve or the laryngeal musculature during surgery. The device will mainly be used in adults, as thyroidectomy is very rarely undertaken in children.

5.3 Predicate Devices

The predicate devices used in this submission are:

- Neurovision LSE500 Laryngeal Surface Electrodes (reference K003745); and
- Medtronic NIM™ EMG Endotracheal Tube (reference K925640).

5.3.1 Comparison with the predicate devices

	Neurosign® Laryngeal Electrode (Subject Device)	Medtronic NIM™ EMG Endotracheal Tube (Predicate Device)	Neurovision LSE500 Laryngeal Surface Electrode (Predicate Device)
Laryngeal surface electrode	Yes	Yes	Yes
Monitoring site	Trachea/larynx	Larynx	Oesophagus
Monitoring type	Continuous EMG monitoring	Continuous EMG monitoring	Continuous EMG monitoring
May be used with all commercial EMG units	Yes	Yes	Yes
Method of electrode attachment	Attached to the surface of the endotracheal tube	Embedded within the endotracheal tube	Attached to the surface of the endotracheal tube
Number of electrodes utilised	2	4	2
Number of channels	2	2	1
Surface of electrode	Conductive ink on a polyester substrate	Stainless steel wire	Carbon w/Ag
Single-use only	Yes	Yes	Yes
Safety characteristics	Non-invasive	Non-invasive	Non-invasive

5.4 Conclusions

The Neurosign® Laryngeal Electrode is both safe and effective and is similar in its risks and benefits, as well as its manner of performance, to the predicate devices listed above (see Section 12 for further discussion).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2007

The Magstim Company, LTD.
c/o Anwen Evans
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Whitland
Carmarthenshire, Wales
United Kingdom, SA34 OHR

Re: K071349
Trade/Device Name: Neurosign® Laryngeal Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator and locator
Regulatory Class: Class II
Product Code: ETN
Dated: May 4, 2007
Received: May 14, 2007

Dear Mr. 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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

M. B. Eydelman, MD

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

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): ~~K944902~~ K071349

Device Name: Laryngeal Electrodes

Indications for Use:

Non-invasively monitoring of the laryngeal nerves during thyroid surgery, and of the Xth cranial nerve during skull-base surgery.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laura H. Baker

(Division Sign-Off)
Ophthalmic Ear, Throat Devises

510(k) Number K07

