K121257

6. 510(k) Summary or 510(k) Statement

AUG 28 2012

510(k) Summary

Manufacturer:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands
Submitted by:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands Tel.: (+31) 43-408 6868 Fax: (+31) 43-408 6888
Contact person:	Mr. Pierre Vreuls Manager Regulatory Affairs & Quality Assurance E-mail: pvreuls@technomed.nl
Date:	April 19, 2012
Proprietary Name:	Laryngeal Electrode
Common/usual Name:	Laryngeal Electrode
Classification Name:	Disposable Laryngeal Electrode is classified as class II per 21 CFR section 874.1820. Product code ETN.
Substantial Equivalence:	K093373: Dragonfly Laryngeal Surface Electrode K071349: Neurosign Laryngeal Electrode
Device description:	Disposable Laryngeal Electrodes are non-invasive. The disposable device is constructed using a medical grade ink as electrode material suspended on a polyethylene substrate; a polyester connector with a separate available cable assembly or DIN 42802 connectors; The electrode is available in three sizes to suit different sexes and age groups. The 4/5mm electrode should be used with an 4 or 5mm endotracheal tube; 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 endotracheal 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 noninvasive, it also lessens the risk of infection during the monitoring procedure.
Intended Use:	The Disposable Laryngeal Electrodes are intended for non-invasive use attached to a endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures with recording and monitoring equipment, (active and reference), of Electromyography (EMG). The electrodes are designed for single-patient application use. The electrodes are intended for use only by a licensed physician.

Comparison to predicates: The design, materials, chemical composition, packaging and other technological characteristics of the subject device is equivalent to those of the predicate devices.

Manufacturer	**Spes Medica s.r.l.**	**The Magstim Company Inc.**	**Technomed Europe**	**Comments to differences**
Device	Dragonfly Laryngeal Surface Electrode	Neurosign Laryngeal Electrode	Laryngeal Electrode	--
510(k) number	*K093373* Predicate device	*K071349* Predicate device	This notification	--
Laryngeal Surface Electrode	Yes	Yes	Yes	Same
Endolaryngeal location	Yes	Yes	Yes	Same
Function with commercial EMG units	Neurovision Medical Products Nerveana Axon Eclipse Medtronic - NIM XLTEK EP Works Nicolet Viking Cadwell Cascade Neurosign Avalanche	Yes	Yes	Same
Method of electrode attachment	Attached to the surface of the endotracheal tube using adhesive backside	Attached to the surface of the endotracheal tube using adhesive backside	Attached to the surface of the endotracheal tube using adhesive backside	Same
Electrode surface	Silver conductive ink on polyester substrate	Conductive ink on polyester substrate	Conductive ink on soft PE substrate	Using a softer substrate material (PE) (see §12.4)
Electrical insulation	On all surfaces except electrodes	On all surfaces except electrodes	On all surfaces except electrodes	Same
Product code	ETN	ETN	ETN	Same
Intended Use/ Indication of Use	The Dragonfly Laryngeal Surface Electrode is intended to be used as disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures. It is intended for use only by a licensed physician and in conjunction with these listed below medical grade electromyographic monitors.	Laryngeal electrodes for non-invasively monitoring of the laryngeal nerves during thyroid surgery, and of the Xth cranial nerve during skull-base surgery.	The Laryngeal Electrode is intended to be used as disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures. It is intended for use only by a licensed physician and in conjunction with a commercially available, medical grade electromyographic monitor.	Same
Sterilization	EtO	Gamma	EtO	Same
Shelf-life (expiry date)	3 years	3 years	3 years	Same
Uses	Disposable	Disposable	Disposable	Same
Method of electrode attachment	Attached to the surface of the endotracheal tube with adhesive	Attached to the surface of the endotracheal tube with adhesive	Attached to the surface of the endotracheal tube with medical grade adhesive	Same
Number of electrodes utilized	4	2	2	Same
Number of channels	2	2 + grounding electrode	2 + grounding electrode	Same
Connector	1.5 mm safety connector DIN 42 802	Polypropylene connector with extension lead to DIN 42 802 safety connector	Polypropylene connector with extension lead to DIN 42 802 safety connector	Same
Safety characterization	Non invasive	Non invasive	Non invasive	Same
Biocompatible according ISO 10993-1:2009	Yes	Yes	Yes	Same

Non-clinical data:	Technomed Europe has been bench testing the Laryngeal Electrodes to confirm performance characteristics of this device. The Technomed Europe Laryngeal electrodes are being bench tested in comparison to the predicated devices, K093373: Dragonfly Laryngeal Surface Electrode and K071349: Neurosign Laryngeal Electrode. The electrode surface, method of electrode attachment to endotracheal tube, electrical insulation, sterilization, shelf-life, intended use, number of electrodes utilized, number of channels, connector, safety characterization, design characterization, impedance, dimensions will be tested.
Conclusion:	The comparison to the predicate devices demonstrate that the Disposable Laryngeal Electrode is safe and effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Technomed Europe
c/o Mr. Pierre Vreuls
Manager Regulatory Affairs & Quality Assurance
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

AUG 28 2012

Re: K121257
Trade/Device Name: Laryngeal Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: August 7, 2012
Received: August 10, 2012

Dear Mr. Vreuls:

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. 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); 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

K121257

5. Indications for Use Statement

Indications for Use

510(k) Number (if known): K121257

Device Name: Laryngeal Electrodes

Indications for Use:

Non-invasively monitoring of the laryngeal nerves during thyroid surgery, and of the X^{th} 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K121257