510 (k) Summary of safety and effectiveness

AUG 2 4 2010

SUBMITTER INFORMATION

A. Company Name:	Spes Medica s.r.l.
B. Company Address:	Via Europa - Zona industriale Battipaglia (SA) – Italy 84091
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D. Contact Person:	Alfredo Spadavecchia Quality Assurance Manager Spes Medica s.r.l. e-mail: a.spadavecchia@spesmedica.com
E. Date Summary Prepared:	October 21, 2009

DEVICE IDENTIFICATION

A. Device name:	Dragonfly Laryngeal Surface Electrodes
B. Trade/Proprietary name:	Dragonfly Laryngeal Surface Electrodes
C. Classification name:	Surgical nerve stimulator/locator (21 CFR §874.1820)
D. Product code:	ETN

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

Predicate device	510(k) Holder/Applicant	510(k) number
LARYNGEAL SURFACE ELECTRODE-ENDOTRACHEAL TUBE	RLN SYSTEM, INK	K003745
NEUROSIGN LARYNGEAL ELECTRODES	THE MAGSTIM COMPANY LTD.	K071349
XOMED-TREACE EMG ENDOTRACHEAL TUBEEN	XOMED-TREACE, INC.	K925640

DEVICE DESCRIPTION

Spes Medica Dragonfly Laryngeal Surface Electrode are single used electrodes for evoked EMG monitoring of the larynx and it to be inserted and retained in position against the laryngeal muscle by use of an endotracheal tube. The Electrodes are intended to be used as disposable, self-adhesive electrodes attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures. Spes Medica produces two different families of electrodes: Family A and Family B.
The family A and B mentioned above are the same product because, have been developed with same intended use, design, materials, packaging and other technological characteristics. The manufacturing processes are the same for both configurations (Family A and Family B) but the substrates and the shape of the electrodes are different. Indeed, for the family A the substrate for the Silver ink is a polyester film and for the family B the substrate for the Silver ink is carbon loaded vinyl. Furthermore, both families use the same connection to the EMG unit.

INTENDED 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:

Manufacturer and Device name
Neurovision Medical Products **Nerveana**
Axon **Eclipse**
Medtronic - **NIM**
XLTEK **EP Works**
Nicolet **Viking**
Cadwell **Cascade**
Neurosign **Avalanche**

SUBSTANTIAL EQUIVALENCE

The Dragonfly Laryngeal Surface Electrodes are similar in intended use, design, materials, packaging and other technological characteristics to the predicate devices.

COMPARISON CHART LARYNGEAL SURFACE ELECTRODES

ATTRIBUTE/ CHARACTERISTICS	DRAGONFLY LARYNGEAL SURFACE ELECTRODES (Submitted Product)		LEGALLY MARKETED PREDICATE DEVICES OF RLN System Inc.	LEGALLY MARKETED PREDICATE DEVICES OF Xomed Treace Inc.	LEGALLY MARKETED PREDICATE DEVICES OF The Magstim Company Ltd.
	FAMILY A	FAMILY B			
"K" numbers	New Device	New Device	K003745	K925640	K071349
Laryngeal surface Electrode	Yes	Yes	Yes	Yes	Yes
Endolaryngeal location	Yes	Yes	Yes	Yes	Yes
Function with commercial EMG units	Yes	Yes	Yes	Yes	Yes
Method of electrode attachment	Attached to the surface of the endotracheal tube	Attached to the surface of the endotracheal tube	Attached to the surface of the endotracheal tube	Embedded within the endotracheal tube	Attached to the surface of the endotracheal tube
Electrode Surface	Silver conductive ink on a polyester substrate	Carbon w/Ag	Carbon w/Ag	Stainless Steel Wire	Conductive ink on a polyester substrate
Monitor site	Trachea/larynx	Trachea/larynx	Trachea/larynx	Trachea/larynx	Trachea/larynx
Monitor type	Continuous EMG monitoring	Continuous EMG monitoring	Continuous EMG monitoring	Continuous EMG monitoring	Continuous EMG monitoring
Single use only	Yes	Yes	Yes	Yes	Yes
Sterilization	ETO	ETO	ETO	ETO	ETO
Safety Characteristics	Non-invasive	Non-invasive	Non-invasive	Non-invasive	Non-invasive
Intended use	The Laryngeal Surface Electrodes 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: Neurovision Medical Products **Nerveana** Axon **Eclipse** Medtronic - **NIM** XLTEK **EP Works** Nicolet **Viking** Cadwell **Cascade** Neurosign **Avalanche**	The Laryngeal Surface Electrodes 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: Neurovision Medical Products **Nerveana** Axon **Eclipse** Medtronic - **NIM** XLTEK **EP Works** Nicolet **Viking** Cadwell **Cascade** Neurosign **Avalanche**	The Laryngeal Surface Electrodes 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	The Xomed EMG Endotracheal Tube is intended for use as a tracheal tube for the administration of anesthesia gases and to maintain an open airway for the patient during the surgery. The EMG electrodes are intended to serve as contact electrodes with the vocal cords of the patient and when connected to an EMG monitor, the wire electrodes facilitate the intra-operative monitoring of the vocal cords for locating and mapping the Recurrent Laryngeal Nerve and its branches during surgery of the neck.	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

CONCLUSION

The Dragonfly Laryngeal Surface Electrodes are similar in intended use, design, materials, packaging and other technological characteristics to the predicate devices. After analyzing performance and safety testing, it is the conclusion of Spes Medica s.r.l. that the Dragonfly Laryngeal Surface Electrodes are safe and effective as the predicate devices and introduce no new questions concerning safety and effectiveness

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

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AUG 2 4 2010

Re: K093373
Trade Name: Dragonfly Laryngeal Surface Electrodes
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: July 19, 2010
Received: July 21, 2010

Dear Mr. Spadavecchia:

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,

Srinivas Nandkumar, Ph.D.
Branch Chief,
Ear, Nose, and Throat Devices Branch
Division of Ophthalmic 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): K093373

Device Name: Dragonfly Laryngeal Surface Electrodes

Indications for 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:

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Cadwell **Cascade**
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Prescription Use___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
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 K093373