K091874
P-1 of 3

510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Inomed Medizintechnik GmbH
Company Address	Tullastrasse 5a Teningen, Germany 79331
Telephone:	49-7641-9414-0
Fax:	49-7641-9414-94
Contact Person:	Sascha Busch
Telephone:	049-7641-9414-87

NOV 18 2009

Summary Preparation Date: March 23, 2009

DEVICE NAME **807.92(a)(2)**

Trade Name:	Inomed Adhesive Laryngeal Electrode
Common/Usual Name:	Laryngeal Electrode,
Classification Name:	Stimulator, Nerve
Regulation Number:	CFR §874.1820
Product Code:	ETN
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Magstim Co.,Ltd.	Neurosign Laryngeal electrodes	K071349
RLN Systems, Inc.	Laryngeal Surface Electrode	K003745

DEVICE DESCRIPTION **807.92(a)(4)**

The Inomed Adhesive Laryngeal Electrodes are single used electrodes constructed from an medical-grade ink with a conductive polymer film covered by an insulating coating, a connector made of polypropylene: and a cable assembly. The electrodes are designed to monitor the recurrent nerve during thyroid, anterior cervical, carotid endartecrectomy surgery and vagus nerve monitoring during brain surgery. The monitoring is performed with a surface electrode that is attached to an endotracheal tube placed on the vocal cord. A neutral adhesive electrode is placed on the patient's shoulder. Both adhesive electrodes are connected to a reusable recording cable and to the nerve monitor

K091874
P. 2 of 3

DEVICE INTENDED USE **807.92(a)(5)**

The Inomed Adhesive Laryngeal Electrodes are intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

Parameters	New Device	Predicate Device	Predicate Device
Device	Inomed Laryngeal Electrode	Neurosign Laryngeal Electrodes	Laryngeal surface Electrode – Endotracheal Tube
Manufacturer	Inomed	Magstim Co., Ltd.	RLN Systems, Inc. (Neurovision Medical)
510(k)	N/A	**K071349:**	**K003745**
Product Code	ETN	ETN	ETN
Intended Use	The Laryngeal Surface Electrode-Endotracheal Tube is intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures.	Laryngeal electrodes intended for non-invasively monitoring the laryngeal nerves during thyroid surgery, and of the Xth cranial nerve during skull-base surgery	The Laryngeal Surface Electrode-Endotracheal Tube is intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures.
Monitoring site	Trachea/larynx	Trachea/larynx	Trachea/larynx
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	Attached to the surface of the endotracheal tube	Attached to the surface of the endotracheal tube
Number of electrodes utilized	2	2	2
Number of channels	2	2	2
Device design	-Medical grade inks suspended in a polyester substrate -polypropylene connector - cable assembly -Adhesive back surface	-Medical grade inks suspended in a polyester substrate -polypropylene connector - cable assembly -Adhesive back surface	-Two-plate laryngeal electrode -adhesive on back surface
Electrical insulation	Electrical insulation on all surfaces until the	Electrical insulation on all surfaces until the	Two plate laryngeal electrode

K091874
P. 3 of 3

	head of the electrode	head of the electrode	
Single use only	Yes	Yes	Yes
Safety characteristics	Non-invasive	Non-invasive	
Biocompatibility ISO 10993-1	Yes		Yes
IEC 60601-1 Protected Pin design	Connector touch proof	Unknown	Unknown
Sterilization	ETO	ETO	ETO

Conclusions:
The Inomed Adhesive Laryngeal Electrodes are similar to the predicate device in intended use and technological characteristics. After analyzing performance and safety testing, it is the conclusion of Inomed that the inomed adhesive laryngeal electrodes are as safe and effective as the predicate devices and introduce no new questions concerning safety and effectiveness.

NONCLINICAL AND CLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS
The Inomed adhesive electrodes have been tested to the appropriate electrical testing standard and biocompatibility standards and have been found safe for their intended use

CONCLUSION **807.92(b)(3)**
Conclusions:
The Inomed Adhesive Laryngeal Electrodes are similar to the predicate device in intended use and technological characteristics. After analyzing performance and safety testing, it is the conclusion of Inomed that the *inomed adhesive laryngeal electrodes* are as safe and effective as the predicate devices and introduce no new questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV 18 2009

Inomed Medizintechnik GmbH
c/o Ms. Yolanda Smith
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K091874
Trade/Device Name: Inomed Adhesive Laryngeal Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: ETN
Dated: October 2, 2009
Received: October 5, 2009

Dear Ms. Smith:

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.

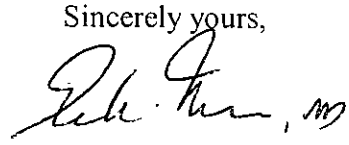
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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): K091874

Device Name: Inomed Adhesive Laryngeal Electrodes

Indications for Use:

The Inomed Adhesive Laryngeal Electrodes are intended to be used as a disposable, self-adhesive electrode attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures.

Prescription Use ___v____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

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

510(k) Number K091874