December 21, 2023

Suzhou Haishen Medical Device Associates Co., Ltd
℅ Xiaoqing Xue
Registration Engineer
Sinow Medical AS
Høyteknologisenteret Thormøhlens Gate 55
Bergen, 5008
Norway

Re: K232888
Trade/Device Name: Disposable Laryngeal Electrodes
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: November 24, 2023
Received: November 24, 2023

Dear Xiaoqing Xue:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232888

Device Name
Disposable Laryngeal Electrode

Indications for Use *(Describe)*
The disposable laryngeal electrodes are intended to be used as a disposable, self-adhesive electrodes attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

K232888

1. Submitter

Submitter: Suzhou Haishen United Medical Device Associates Co., Ltd
Address: 3F, 4F 401, 4F 402, 5F, Building 10, No. 168 Majian Road,
Suzhou, Jiangsu Province, China
Telephone: +86 18921623557
Email: 785445240@qq.com
Contact Person: Leyi Dai
Date Prepared: Dec.15, 2023

2. Designated Submission Correspondent

Company: Sinow Medical AS
Address: Vestre Fantoftåsen 44, 5072, Bergen, Norway
Contact Person: Xiaoqing Xue
Telephone: +86 15161196032
Email: xue@bergemed.com

3. Subject Device

Trade name: Disposable Laryngeal Electrodes
510(K) number: K232888
Regulatory Class: II
Regulation Number: 21 CFR 874.1820
Product Codes: ETN
Classification Panel: Ear Nose & Throat
Classification Name: Stimulator, Nerve

4. Primary Predicate Device

Manufacturer: Inomed Medizintechnik GmbH
Trade name: Inomed Adhesive Laryngeal Electrode
510(K) Number: K091874
Regulation Number: 21 CFR 874.1820
Product Codes: ETN
Classification Panel: Ear Nose & Throat
Classification Name: Stimulator, Nerve

5. Device Description

The Disposable 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.

6. Intended Use/Indications for Use

The Disposable 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.

7. Comparison of Technological Characteristics

Attribute	Disposable Laryngeal Electrode (Subject Device)	Inomed Adhesive Laryngeal Electrode (Predicate device K091874)	Comment
Regulation Number	21 CFR 874.1820	21 CFR 874.1820	Same
Regulation Name	Surgical nerve stimulator/locator	Surgical nerve stimulator/locator	Same
Regulatory Class	Class II	Class II	Same
Product Code	ETN	ETN	Same
Indications for Use	The Disposable 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.	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.	Same
Monitoring site	Trachea/larynx	Trachea/larynx	Same
Monitoring type	Continuous EMG monitoring	Continuous EMG monitoring	Same
May be used with all commercial EMG units	Yes	Yes	Same
Method of electrode attachment	Attached to the surface of the endotracheal tube	Attached to the surface of the endotracheal tube	Same
Number of electrodes utilized	2	2	Same
Number of channels	2, 4	2	Different [1]
Device design	-Medical grade inks suspended in a polyester substrate	-Medical grade inks suspended in a polyester substrate	Same

	-polypropylene connector -cable assembly	-polypropylene connector -cable assembly	
Electrical insulation	Electrical insulation on all surfaces until the head of the electrode	Electrical insulation on all surfaces until the head of the electrode	Same
Single use only	Yes	Yes	Same
Safety characteristics	Non-invasive	Non-invasive	Same
Sterilization	ETO	ETO	Same

Discussion of difference [1]: The subject device included two and four channels type.The predicate device only have two channels type. Although differences between numbers of channel, the subject two and four channel device have the same design, materials and intended performance, only increasing two identical channels. Furthermore, the four channel device is selected as representative sample to performed electrical safety testing according to IEC 60601-1 to ensure meet the electrical safety requirement. Therefore, we considered that this difference does not raise new questions of safety or effectiveness.

8. Non-Clinical Testing

8.1. Performance Testing-Bench

Suzhou Haishen United Medical Device Associates Co., Ltd has performed the following non-clinical laboratory testing to determine substantial equivalence.

Test	Acceptable criteria	Result
Adhesive property	The electrode should be able to be firmly adhered.	Pass
Electrode Impedance	Each path of the electrode should be able to conduct, impedance: ≤100Ω.	Pass
Security	Normal state (μA): AC: ≤0.01mA (10μA) and DC: ≤0.1mA(100μA） Application part pressurized state (mA)：≤5mA	Pass
Sterility testing	The products were sterile both before and after aged.	Pass

The essential performance and safety of Disposable Laryngeal Electrode was tested for performance in accordance with internal requirements. The adhesive property, electrode Impedance and security were evaluated for subject and predicate device to ensure that the subject device performed as intended and supported substantial equivalence to the predicate devices.

8.2. Biocompatibility testing

The contact classification for the Disposable Laryngeal Electrode of the subject device is a surface contact device that directly contact with the mucosal membrane (≤24h). The biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and in accordance with FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff. The results of biocompatibility

testing included in the table below demonstrate that the device meets biological safety requirements per ISO 10993-1 for mucosal membrane contact device.

Test	Standard	Result
In vitro cytotoxicity	ISO 10993-5	Non-cytotoxic
Skin sensitization	ISO 10993-10	Non-sensitive
Intracutaneous reactivity	ISO 10993-23	Non- irritation
Acute systemic toxicity	ISO 10993-11	Non-acute systemic toxicity
Pyrogen	ISO 10993-11	Non-pyrogenic

8.3. Sterilization and shelf-life testing

The subject device is sterilized using Ethylene Oxide. The sterilization validation has been performed in accordance with the principles of ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The device meets EO residuals per ISO 10993-7.
A shelf-life of 3 years has been established based on accelerated aging testing.

8.4. Electrical safety testing

Suzhou Haishen United Medical Device Associates Co., Ltd has performed the electrical safety testing according to IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance. Testing were performed and confirmed that the subject device is meet the requirement.

9. Conclusion

The Disposable Laryngeal Electrode is substantially equivalent to the predicate device when evaluating intended use and technological characteristics. The subject device has the identical intended use as the predicate device and only has a minor technological difference that does not raise different questions of safety or effectiveness. The nonclinical performance data submitted in the 510(k) demonstrates the subject device is substantially equivalent to the predicate device.