December 4, 2023

Suzhou Haishen Medical Device Associates Co., Ltd
℅ Jie Gao
Consultant
Sinow Medical AS
Høyteknologisenteret Thormøhlens Gate 55
Bergen, 5008
Norway

Re: K232581
Trade/Device Name: Medical Disposable Sterile Needle Electrode
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: August 23, 2023
Received: August 25, 2023

Dear Jie Gao:

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,

FDA Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,

Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*

Device Name
Medical Disposable Sterile Needle Electrode

Indications for Use *(Describe)*
This product is intended for use with recording, monitoring equipment for the recording of bioelectrical signals, such as electromyograph (EMG). The electrodes are sterile and for single patient use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

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III. DEVICE

Trade Name: Medical Disposable Sterile Needle Electrode

Classification Name: Needle Electrode

Regulatory Class: II

Product Code: GXZ

IV. PREDICATE DEVICE

Product Name: Subdermal Needle Electrodes

510(k) Number: K072276

Product Code: GXZ

Manufacture: Xian Friendship Electronics Co., Ltd.

V. DEVICE DESCRIPTION

Medical disposable sterile needle electrodes are sterile, single use products that penetrate the skin and directly contact the extracellular fluid during use, forming a good electrode-electrolyte interface. The pointed part of the needle electrode makes contact with the nerves, muscles, or

other tissues under examination to collect and transmit the corresponding bioelectrical signals (myoelectric currents) to the electromyography (EMG) recorder. Needle electrodes are used in conjunction with EMG diagnostic instruments and serve as accessories to the EMG machine for detecting myoelectric potentials. Medical disposable sterile needle electrodes are invasive since they are positioned subcutaneously and are used under the supervision of a licensed physician.

The subject device, available in configurations with and without lead wires, which encompasses subdermal, monopolar, spiral, and concentric designs. The subject device's configurations of monopolar and concentric needles correspond to those without lead wires, while the configurations involving spiral and subdermal designs include lead wires.

VI. INDICATIONS FOR USE

This product is intended for use with recording, monitoring equipment for the recording of bioelectrical signals, such as electromyograph (EMG). The electrodes are sterile and for single patient use only.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological characteristics comparing to the predicate device are outlined in the Substantial Equivalent table.

Attribute	Medical Disposable Sterile Needle Electrodes (Subject Device)	Friendship Subdermal Needle Electrodes (Predicate device K072276)	Comment
Regulation Number	21 CFR 882.1350	21 CFR 882.1350	SE
Regulation Name	Needle Electrode	Needle Electrode	SE
Regulatory Class	Class II	Class II	SE
Product Code	GXZ	GXZ	SE
Indications for Use	This product is intended for use with recording, monitoring equipment for the recording of bioelectrical signals, such as electromyograph (EMG). The electrodes are sterile and for single patient use only.	Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal	Subject Device without stimulation function; Subject Devie only records in EMG

		axonal conduction. The electrodes are sterile and for single patient use only.	
Environment of Use	Hospital	Hospital	SE
Provided Sterile	Yes	Yes	SE
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	SE
Sterility assurance level (SAL)	10^{-6}	10^{-6}	SE
Single Use, Disposable	Yes	Yes	SE
Basic Principle	A needle electrode is an electrode that requires penetration through the skin to directly contact extracellular fluid. It forms a good electrode-electrolyte interface and is used in conjunction with electromyography (EMG) diagnostic instruments as an electrode for detecting muscle electrical activity.	A needle electrode is an electrode that requires penetration through the skin to directly contact extracellular fluid. It forms a good electrode-electrolyte interface and is used in conjunction with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction.	Same basic principle but Subject Device has less clinical usage than Predicate Device
Target Population	Adults, children and infants	Adults, children and infants	SE
Anatomical Sites	Subdermal, muscle tissue	Subdermal, nerve or muscle tissue	Subject Device has less Anatomical Sites
Needle material	Stainless steel	Stainless steel	SE
Needle length	Spiral needle: 20 ± 1.5mm Concentric needle: (20 - 75) ± 1.5mm Subdermal needle:	Spiral needle: NA Concentric needle: 20 - 75mm Subdermal needle:	Equivalent

	(6, 7, 13, 19, 20, 22) ± 1.5mm Monopolar needle: (20, 25, 30, 37, 50, 75) ± 1.5mm	7, 13, 17, 23mm Monopolar needle: 20, 25, 30, 38, 50, 75mm	
Needle diameter	Spiral needle: 0.60 ± 0.15mm Concentric needle: (0.25 - 0.65) ± 0.15mm Subdermal needle: (0.35, 0.40, 0.45) ± 0.15mm Monopolar needle: (0.25, 0.30, 0.35, 0.40, 0.45, 0.50, 0.65) ± 0.15mm	Spiral needle: 0.60 mm Concentric needle: 0.25 - 0.65mm Subdermal needle: 0.35, 0.40, 0.45mm Monopolar needle: 0.25, 0.30, 0.35, 0.40, 0.45, 0.50, 0.65mm	Equivalent
Lead wire material	PVC insulated tin plated with copper	PVC insulated tin plated with copper	SE
Lead wire length	(1000 - 2500) ± 25mm	1200 - 2500mm	Equivalent

VIII. NON-CLINCAL TESTING

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

Test	**Result**
Surface quality	Pass
Sharpness index	Pass
Toughness	Pass
Connection strength	Pass
Electrical conductivity	Pass
Conductive terminals and needle body insulation	Pass
Sterility testing	Pass

IX. BIOCOMPATIBILITY TESTING

The contact classification for the Medical Disposable Sterile Needle Electrode component of the subject device is a subdermal communicating device with muscle. 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 subdermal communicating devices with muscle.

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

X. 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 and real-time aging.

XI. CONCLUSIONS

The subject and predicate device share the same intended use – for temporary use with recording and monitoring equipment for the recording and monitoring of bioelectrical signals from the corresponding muscle parts of the human body, such as electromyography (EMG). The subject device does not have stimulation function as the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the nonclinical performance data submitted in the 510(k) demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.