September 25, 2024

Dongguan Quanding Medical Supplies Co., Ltd.
℅ Jett Li
Regulation Manager
Guangzhou KEADA Biological Tech Co., Ltd.
6F, No.1 TianTai road
Science City, LuoGang District
GuangZhou, Guangdong 510000
China

Re: K242204
Trade/Device Name: Disposable Neutral Electrodes (GP201B-A, GP202B-A, GP202B-P, GP202B-I, GP202M-A, GP202M-P, GP202M-I, GP202B-AC, GP202B-PC, GP202B-IC, GP202M-AC, GP202M-PC, GP202M-IC, GP203M-A, GP203B-A, GP203M-AC, GP203B-AC, GP203M-P, GP203B-P, GP203M-PC, GP203B-PC, GP203M-I, GP203B-I, GP203M-IC, GP203B-IC)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 23, 2024
Received: July 26, 2024

Dear Jett Li:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.09.25 09:02:55 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242204

Device Name

Disposable Neutral Electrodes (GP201B-A, GP202B-A, GP202B-P, GP202B-I, GP202M-A, GP202M-P, GP202M-I, GP202B-AC, GP202B-PC, GP202B-IC, GP202M-AC, GP202M-PC, GP202M-IC, GP203M-A, GP203B-A, GP203M-AC, GP203B-AC, GP203M-P, GP203B-P, GP203M-PC, GP203B-PC, GP203M-I, GP203B-I, GP203M-IC, GP203B-IC)

Indications for Use *(Describe)*

Disposable neutral electrodes are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient.
Solid Electrosurgical pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical pads are for use with generators that have a CQMS (i.e. REM,ARM,NESSY etc.).

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1 510 (k) submitter

1.1 Sponsor

Company Name: Dongguan Quanding Medical Supplies Co., Ltd.

Address: No.3 Yongfa East Road, Dongshan, Qishi Town, Dongguan City, Guangdong, China

Phone: +86- 189 2372 2306

Email: 2851139778@qq.com

Contact Person (including title): Grace Zhao (General Manager)

1.2 Application Correspondent

Guangzhou KEADA Biological Tech Co., Ltd.

Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

Contact Person: Mr. Jett Li

Title: Regulation Manager

Tel: +86-13512755282

Email: jianda-lee@foxmail.com

2 Date Prepared

2024-01-23

3 Subject Device Information

- Trade Name: Disposable Neutral Electrodes
- Common Name: Disposable Neutral Electrodes
- Classification Name: Electrosurgical cutting and coagulation device and accessories

- Review Panel: General & Plastic Surgery
- Product Code: GEI
- Regulation Number: 21 CFR 878.4400
- Regulation Class: 2

4 Predicate device Information

Legally marketed device K203494

Trade Name: Nissha Medical Technologies Neutral Electrodes

Classification Name: Electrosurgical cutting and coagulation device and accessories

Review Panel: General & Plastic Surgery

Product Code: GEI

Regulation Number: 21 CFR 878.4400

Regulation Class: 2

5 Device Description

Disposable neutral electrodes are part of a family of patient return electrodes. They are non-sterile, single-use devices used in electrosurgery to complete the electrical circuit with the generator. Providing a low-impedance path back to the generator through the return electrodes helps to prevent unintended HF burns. The solid electrosurgical pads are designed to be compatible with generators without Contact Quality Monitoring System (CQMS), and the split electrosurgical pads are designed to be compatible with the Contact Quality Monitoring System (CQMS) of compatible generators. The models share the same design elements (functional design, technology design, packaging, etc.) but have different sizes and shapes. The models are designed for adults, children, and neonates, separate catalog numbers are assigned for the intended patients, and pre-attached cord.

Disposable neutral electrodes consist of foam backing, cable connection area, conductive aluminum foil, conductive adhesive gel layer and release liner. The pads are applied on a release liner. The surface of the conductive aluminum foil is fully covered with a soft, conformable conductive adhesive gel.

The electrode backing is made of foam material. The electrodes are supplied with or without cable. For the non-corded pads, a reusable cable is not available as an accessory.

6 Indications for Use

Disposable neutral electrodes are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient.

Solid Electrosurgical pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical pads are for use with generators that have a CQMS (i.e. REM,ARM,NESSY etc.).

7 Complied Standards

IEC60601-1	Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-2-2: 2017	Medical electrical equipment- Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
ISO 10993-5:2009	biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity.
ISO 10993-10:2010	biological evaluation of medical devices - part 10: tests for skin sensitization.
ISO 10993-23: 2021	biological evaluation of medical devices - part 10: tests for irritation

8 Performance Testing

As part of demonstrating safety and effectiveness of Nissha Medical Technologies Neutral Electrodes and in showing substantial equivalence to the predicate devices, Nissha Medical Technologies completed several non-clinical performance tests. The Nissha Medical Technologies Neutral Electrodes meet all the requirements for overall design, biocompatibility and electrical safety with results confirming that the design output meets the design inputs and specifications for the devices.

The Nissha Medical Technologies Neutral Electrodes passed all the testing in accordance with internal requirements, and international standards shown below to support substantial equivalence of the predicate devices:

- The device passed performance testing conducted according to standard IEC 60601-2-2:2017 "Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories" and IEC 60601-1, relevant requirements. The testing conducted included: Thermal performance, Contact impedance, Adhesion, Shelf-life, Cord attachment, Cord connector and Cord insulation.
- Biocompatibility testing per ISO 10993-1 confirmed that the finished devices are biocompatible, and do not induce new risks. Testing per ISO 10993-5 Cytotoxicity was showing a slight reactivity, and ISO 10993-10 (Skin Irritation and Sensitization) was showing no adverse results.

Shelf Life Testing – According to accelerated aging of the Nissha Medical Technologies Neutral Electrodes and subsequent electrical safety testing, as it is required in subclause 201.15.101.8 of the standard IEC 60601-2-2, it has been demonstrated that the Nissha Medical Technologies Neutral Electrodes can be labeled with a shelf-life of 24 months.

9 Biocompatibility

Biocompatibility testing per ISO 10993-1 confirmed that the finished devices are biocompatible, and do not induce new risks. Testing per ISO 10993-5 Cytotoxicity was showing a slight reactivity, and ISO 10993-10 (Skin Irritation and Sensitization) was showing no adverse results.

10 Clinical Performance

No human clinical testing is required to support the medical device as the intended use is equivalent

to the predicate devices. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11 Comparison with Predicate Device

Description	Subject Device	Predicate Device	Device Comparison
Manufacturer	Dongguan Quanding Medical Supplies Co., Ltd.	Nissha Medical Technologies Ltd.	-
510(k) Number	-	K203494	-
Product Code	GEI	GEI	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Same
Indications for Use	Disposable neutral electrodes are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient. Solid Electrosurgical pads are for use with generators that do not have a Contact Quality Monitoring System (CQMS). Split Electrosurgical pads are for use with generators that have a CQMS (i.e. REM,ARM,NESSY etc.).	Nissha Medical Technologies Neutral Electrodes - SWAROPLATE: Neutral electrodes are an accessory for monopolar HF-surgery and represent the large area and low impedance contact with the patient's skin required for returning the electric current to the HF-generator. Neutral electrodes are self-adhesive, ready-to-use disposable products. The SWAROPLATE neutral electrodes of Nissha Medical Technologies are not intended for use in High Current Mode. These are applications with high current and / or long activation periods where heating factors of more than 30 A2s in a 60 s period occur.	Words is different, but the Indications for Use is identical

Description	Subject Device	Predicate Device	Device Comparison
		Nissha Medical Technologies Neutral Electrodes – Boston Scientific: Neutral electrodes are an accessory for monopolar HF-surgery and represent the large area and low impedance contact with the patient's skin required for returning the electric current to the HF-generator. Neutral electrodes are self-adhesive, ready-to-use disposable products. The Boston Scientific Neutral Electrodes REF DGP-PMC2-5, REF DGP-PMC2-25, REF DGP-PM2-5, and REF DGP-PM2-25 are intended to be used in combination with the devices "Boston Scientific G4™ and 1A/1B Radiofrequency Generators".	
Prescription or OTC	Prescription	Prescription	Same
Mechanism of Action	Disposable neutral electrodes are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient.	Neutral electrodes serve to return the current from the patient to the electrosurgical unit (ESU) during HF surgery in monopolar application.	Words is different, but the Mechanism of Action is identical
Technology Overview	Multi-layer device consisting of:	Multi-layer device consisting of:	Similar

Sponsor: Dongguan Quanding Medical Supplies Co., Ltd.

Subject Device: Disposable Neutral Electrodes

Description	Subject Device	Predicate Device	Device Comparison
	Conductive aluminum foil Backing material Conductive adhesive gel layer Release liner	Backing material Conductive layer Conductive adhesive hydrogel Cover material	
Population	Neonates, Children, Adults	Neonates, Children, Adults	Same
Anatomical Location	Select a well convex area (muscle) next to the area to be operated but at least 20 cm far from it, possibly on the forearm, on the thigh or on a whip.	Muscular or well vascularized convex skin site, as close as possible to the operating field	Similar
Weight range according to IEC 60601-2-2	>15kg: Adults Between 5 and 15kg: Children <5kg: Neonates	>15kg (33lbs) Adults >5kg (11lbs) Children and Adults Between 5 and 15kg (11 to 33lbs) Children <5kg (11lbs) Neonates	Similar
Conductive area	>15kg Adults: 130-173 cm^2 Between 5 and 15kg Children: 65-94cm^2 <5kg Neonates: 65-94 cm^2	128-170 cm^2 Adults 105 - 110 cm^2 Children and Adults 71 - 72 cm^2 Children 32-37 cm^2 Neonates	Similar *Note 1
Power	Adults not limited Children and Adults not limited Children limited to 250W Neonates limited to 150W	Adults not limited Children and Adults not limited Children limited to 250W Neonates limited to 150W	Similar
Material	Polymer foam or nonwovens Aluminum foil Adhesive gel Release liner	Conductive laminate: Al-foil / PET and medical grade hydrogel Backing: PE-foam Cover: release liner	Similar
Cable length for prewired electrodes	3 meters	3 meters	Same
Self-adhesive	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Single-Use /disposable	Yes	Yes	Same

Description	Subject Device	Predicate Device	Device Comparison
Shelf Life	24 months	24 months	Same
Complies with ISO 10993-1; 10993- 5 and 10993-10	Yes	Yes	Same
Complies with relevant clauses of IEC 60601-2-2	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same
Compatibility with HF Generators (ESU)	Yes, several ESUs have been evaluated for compatibility.	Yes, several ESUs have been evaluated for compatibility and a "Declaration of Compatibility" is available for end-users.	Similar
Packaging	Sealed pouch	Sealed pouch	Same
Accessory	For electrodes provided without cable, reusable cable available	For electrodes provided without cable, reusable cable available	Same

Note 1: The subject device has a similar conductive area as compared to the reference device no matter adults, neonates, and children.

The only obvious difference is that the maximum conductive area of the neonates model is larger than that of the predicate device. As is well known to all, when dispersive electrodes with larger areas were used, the maximum temperature decreases. with the areas raised. Also consider that the subject device has passed IEC60601-1, EN60601-1-2, IEC 60601-2-2 tests.

Thus, the subject device has same safety features in thermal performance than the reference device, the difference in conductive areas will not affect the safety and effectiveness of the subject device.

12 Statement of Substantial Equivalence

The Disposable Neutral Electrodes have the same indications for use, technological characteristics, and performance characteristics as the predicate devices. Electrosurgical Pads is as safe, as effective, and performs as well as the predicate devices.