February 23, 2021

Nissha Medical Technologies LTD
Marcel Salchner
Director of European Quality, Regulatory & Innovation
Torbay Business Park, Woodview Road
Paignton, Devon TQ4 7HP
United Kingdom

Re: K203494
Trade/Device Name: Nissha Medical Technologies Neutral Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 29, 2020
Received: December 30, 2020

Dear Marcel Salchner:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203494

Device Name
Nissha Medical Technologies Neutral Electrodes

Indications for Use *(Describe)*

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.

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".

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.

510(k) Summary
Nissha Medical Technologies Neutral Electrodes

1) Submission Sponsor/Correspondent
Nissha Medical Technologies Ltd.
Torbay Business Park, Woodview Road
Paignton, Devon TQ4 7HP
United Kingdom
Establishment Registration Number: 3008933393
Contact: Marcel Salchner
Title: Director of European Quality, Regulatory & Innovation
Phone: +43 512 219313
Email: msalchner@nisshamedical.com

2) Date Prepared
2020-12-29

3) Device Identification
Trade Name:	Nissha Medical Technologies Neutral Electrodes
Common Name:	Neutral Electrodes
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Review Panel:	General & Plastic Surgery

4) Legally Marketed Predicate Device(s)
Manufacturer	BOWA-electronics GmbH & Co. KG
Trade Name	BOWA Neutral Electrodes
510(k) Number	K173877 Primary predicate

5) Indication for Use Statement

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 A^2s in a 60 s period occur.

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".

6) Device Description

A neutral electrode is a non-sterile non-active dispersive conductor intended to be fastened to a patient and connected to an electrosurgical diathermy generator, to create a circuit for the return of electrical current to the generator after its emission to perform electrosurgery on the patient. It is fastened to the patient's body typically where the greatest surface area can be covered in closest proximity to the surgical site. It may or may not include a return cable(s). This medical device is intended for single-use.

7) Substantial Equivalence Discussion

The following table compares the Nissha Medical Technologies Neutral Electrodes to the predicate devices with respect to intended use, indications for use, principles of operation, technological characteristics, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate devices.

Table 1 – Comparison of Characteristics

Manufacturer	**BOWA-electronics GmbH & Co. KG**	**Nissha Medical Technologies Ltd.**	**Device Comparison**
Trade Name	BOWA Neutral Electrodes	Nissha Medical Technologies Neutral Electrodes	N/A
510(k) Number	K173877	K203494	N/A
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 self adhesive, ready-to use and single-use products and are an accessory for HF surgery in monopolar applications. The electrodes	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-	Wording is different, but the Intended Use is identical

Manufacturer	BOWA-electronics GmbH & Co. KG	Nissha Medical Technologies Ltd.	Device Comparison
	complete the electrical circuit between the patient and the HF generator on the passive side.	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 A^2s in a 60 s period occur. <u>Nissha Medical Technologies Neutral Electrodes – Boston Scientific:</u> 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	Neutral electrodes serve to return the current from the patient to the electrosurgical unit (ESU) during HF surgery in monopolar application.	Neutral electrodes serve to return the current from the patient to the electrosurgical unit (ESU) during HF surgery in monopolar application.	Same
Technology Overview	Multi-layer device consisting of:	Multi-layer device consisting of:	Similar

NISSHA MEDICAL TECHNOLOGIES	**Nissha Medical Technologies Neutral Electrodes – 510(k) Submission**

Manufacturer	**BOWA-electronics GmbH & Co. KG**	**Nissha Medical Technologies Ltd.**	**Device Comparison**
	Backing material Conductive layer Conductive adhesive hydrogel Cover material	Backing material Conductive layer Conductive adhesive hydrogel Cover material	
Population	Neonates, Children, Adults	Neonates, Children, Adults	Same
Anatomical Location	Muscular or well vascularized convex skin site, as close as possible to the operating field	Muscular or well vascularized convex skin site, as close as possible to the operating field	Same
Weight range according to IEC 60601-2-2	>15kg (33lbs) Adults >5kg (11lbs) Children and Adults Between 5 and 15kg (11 to 33lbs) Children <5kg (11lbs) Neonates	>15kg (33lbs) Adults >5kg (11lbs) Children and Adults Between 5 and 15kg (11 to 33lbs) Children <5kg (11lbs) Neonates	Same
Conductive area	140 cm² Adults 110 cm² Children and Adults 70 cm² Children 40 cm² Neonates	128-170 cm² Adults 105 - 110 cm² Children and Adults 71 - 72 cm² Children 32-37 cm² Neonates	Similar
Power	140 cm² not limited 110 cm² not limited 70 cm² limited to 200W 40 cm² limited to 100W	Adults not limited Children and Adults not limited Children limited to 250W Neonates limited to 150W	Similar
Material	Conductive laminate: Al-foil / PET and medical grade hydrogel Backing: PE-foam Cover: release liner	Conductive laminate: Al-foil / PET and medical grade hydrogel Backing: PE-foam Cover: release liner	Same
Cable length for pre-wired electrodes	3 meters	3 meters	Same
Self-adhesive	Yes	Yes	Same

Manufacturer	BOWA-electronics GmbH & Co. KG	Nissha Medical Technologies Ltd.	Device Comparison
Sterile	Non-sterile	Non-sterile	Same
Single-Use / disposable	Yes	Yes	Same
Shelf Life	36 months	24 months	Similar
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, if ESU is equipped with a CQM System which fulfils IEC 60601-1	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

8) Non-Clinical Performance Data

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) Clinical Performance Data

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.

10) Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. All the comparisons described in this document clearly show that the neutral electrodes from Nissha Medical Technologies are substantially equivalent to the competitor products from BOWA. Despite small differences in detail, all products comply with the state of the art and are suitable for the intended use.