February 15, 2018

BOWA-electronics GmbH & Co. KG
% Roxana Cernescu
Senior Consultant QA/RA
EMERGO Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K173877
Trade/Device Name: BOWA 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 21, 2017
Received: December 21, 2017

Dear Roxana Cernescu:

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. 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); 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K173877

Device Name
BOWA Neutral Electrodes

Indications for Use *(Describe)*
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 complete the electrical circuit between the patient and the HF generator on the passive side.

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

DEVICE NAME

K__173877__

1. Submission Sponsor

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4 - 10

Gomaringen

72810

GERMANY

Contact: Wolf-Ruediger FRITZ

Title: Head of Quality Management / Regulatory Affairs Director

2. Submission Correspondent

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Contact: Roxana CERNESCU

Title: Senior Consultant, Regulatory

3. Date Prepared

2018-01-22

4. Device Identification

Trade Name:	BOWA 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

Classification Panel: General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Manufacturer	**Leonhard Lang GmbH**	**Leonhard Lang GmbH**
Trade Name	**Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 Gel**	**Skintact® Neutral Electrodes for Neonates**
510(k) Number	K063161 Primary predicate	K140500 Secondary predicate

6. Indication for Use Statement

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 complete the electrical circuit between the patient and the HF generator on the passive side.

7. Device Description

BOWA Neutral Electrodes for adults, children and neonates provide a safe return path for electrosurgical current. The electrode consists of a conductive adhesive area surrounded by a non-conductive border adhesive. The conductive area is split in longitudinal or circumferential direction which enables a quicker detection of disconnection. The electrode backing is fluid resistant. The neutral electrode is single-use only, disposable, and non-sterile. The electrodes are supplied with or without a pre-attached cable. For the non-pre-corded electrodes, a reusable cable is available as accessory.

8. Substantial Equivalence Discussion

The following table compares the BOWA 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 5A – Comparison of Characteristics

Manufacturer	**BOWA-electronics GmbH & Co. KG**	**Leonhard Lang GmbH**	**Leonhard Lang GmbH**	**Device Comparison**
Trade Name	**BOWA Neutral Electrodes**	**Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 Gel**	**Skintact® Neutral Electrodes for Neonates**	
510(k) Number	K173877	K063161	K140500	N/A
Product Code	GEI	GEI	GEI	Same
Regulation Number	21 CFR 878.4400	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	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 complete the electrical circuit between the patient and the HF generator on the passive side.	Skintact Cool Contact Electrosurgical Grounding Plates are designed for use with electrosurgical generators for cutting and coagulation of human tissue.	Skintact Neutral Electrodes for Neonates are designed for use with electrosurgical generators for cutting and coagulation of human tissue of newborn or prematurely born patients of between approximately 1 and 11 lbs (0.45 kg and 4.99 kg)	Wording is different, but the Intended Use is the same, reference Section 12, 12.2.1.
Prescription or OTC	Prescription	Prescription	Prescription	Same

Manufacturer	**BOWA-electronics GmbH & Co. KG**	**Leonhard Lang GmbH**	**Leonhard Lang GmbH**	**Device Comparison**
Trade Name	**BOWA Neutral Electrodes**	**Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 Gel**	**Skintact® Neutral Electrodes for Neonates**	
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.	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: Backing material Conductive layer Conductive adhesive hydrogel Cover material	Multi-layer device, details of the layers are not known	Multi-layer device, details of the layers are not known	Similar
Population	Neonates, Children, Adults	Children and Adults	Neonates	The combination of Children, Adults and Neonates leads to the Same population
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	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	>15kg (33lbs) >5kg (11lbs) Between 5 and 15kg (11 to 33lbs)		Same Same Same

Manufacturer	**BOWA-electronics GmbH & Co. KG**	**Leonhard Lang GmbH**	**Leonhard Lang GmbH**	**Device Comparison**
Trade Name	**BOWA Neutral Electrodes**	**Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 Gel**	**Skintact® Neutral Electrodes for Neonates**	
	<5kg (11lbs) Neonates		Between 0.45 and 4.99kg (1lbs to 11lbs)	Same
Conductive area	140 cm² Adults 110 cm² Children and Adults 70 cm² Children 40 cm² Neonates	118 cm² 107 cm² 66 cm²	34 cm²	Similar Similar Similar Similar
Power	140 cm² not limited 110 cm² not limited 70 cm² limited to 200W 40 cm² limited to 100W	118 cm² not limited 107 cm² not limited 66 cm² limited to 120W	34 cm² maximum Watt must be determined for mode of operation	Similar Same Similar 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	Not exactly known	Same
Self-adhesive	Yes	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Single-Use / disposable	Yes	Yes	Yes	Same
Shelf Life	36 months	24 months	24 months	Similar
Complies with ISO 10993-1;	Yes	Yes	Yes	Same

Manufacturer	BOWA-electronics GmbH & Co. KG	Leonhard Lang GmbH	Leonhard Lang GmbH	Device Comparison
Trade Name	**BOWA Neutral Electrodes**	**Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 Gel**	**Skintact® Neutral Electrodes for Neonates**	
10993-5 and 10993-10				
Complies with relevant clauses of IEC 60601-2-2	Yes	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Yes	Same
Compatibility with HF Generators (ESU)	Yes, if ESU is equipped with a CQM System which fulfils IEC 60601-1	Yes, if ESU is equipped with a CQM System which fulfils IEC 60601-1	Yes, if ESU is equipped with a CQM System which fulfils IEC 60601-1	Same
Packaging	Sealed pouch	Sealed pouch	Sealed pouch	Same
Accessory	For electrodes provided without cable, reusable cable available	For electrodes provided without cable, reusable cable available	For electrodes provided without cable, reusable cable available	Same

9. Non-Clinical Performance Data

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

The BOWA 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 60601-2-2:2009 "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: Contact impedance for new and aged devices, Resistance, Shelf-life, Isolation of active accessory, Patient lead.

- Biocompatibility testing per ISO 10993-1 confirmed that the finished devices are biocompatible, and do not induce new risks. The following testing per ISO 10993-5 Cytotoxicity, and ISO 10993-10 (Skin Irritation and Sensitization) shown no adverse results.

- Shelf Life Testing – According to real time aging of the BOWA Neutral Electrodes and subsequent electrical safety testing it could be proven that the BOWA Neutral Electrodes can be labeled with a shelf-life of 36 (thirty-six) months.

- Reprocessing Testing – The BOWA Neutral Electrodes Cable reusable was subject to extensive reprocessing procedures simulating recommended procedures, as manual cleaning and disinfection, automated cleaning and disinfection as well as steam sterilization. Subsequently the main components of the cable were subject to electrical safety testing which proved that all requirements could be fulfilled.

10. 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.

11. 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. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The BOWA Neutral Electrodes, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.