April 2, 2020

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

Re: K193591
Trade/Device Name: ARC 400
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 20, 2019
Received: April 2, 2020

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. 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)*
K193591

Device Name
ARC 400 Electrosurgical Unit

Indications for Use *(Describe)*
The High Frequency (HF) device is intended exclusively for the generation of electrical power for monopolar and bipolar cutting and coagulation of tissue structures in surgical operations.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

ARC 400 Electrosurgical Unit

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

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Office Phone: (512) 327-9997
Email: LST.AUS.ProjectManagement@ul.com
Contact: Roxana CERNESCU
Title: Senior Consultant QA/RA

3. Date Prepared

February 6, 2020

4. Device Identification

Proprietary Name:	ARC 400
Part Number:	900-400
Common/Usual Name:	Electrosurgical Device
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Class:	2
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Device name:	AUTOCON III 400
510(k) number:	K171717
Manufacturer:	KARL STORZ SE & Co. KG

6. Indication for Use Statement

The High Frequency (HF) device is intended exclusively for the generation of electrical power for monopolar and bipolar cutting and coagulation of tissue structures in surgical operations.

7. Device Description

The ARC 400 (REF: 900-400) is an electrosurgical device. It generates high frequency (HF) electrical current for the purpose of cutting (e.g. removing tissue) or coagulating (e.g. control bleeding) human tissue. It is used with compatible bipolar instruments (e.g. K953509) or with monopolar instruments (e.g. K982743) in combination with a neutral electrode (e.g. K173877).

The ARC 400 offers 34 modes that represent four main categories: monopolar cutting (12 modes), monopolar coagulation (9 modes), bipolar cutting (4 modes) and bipolar coagulation (9 modes).

8. Substantial Equivalence Discussion

The following table compares the ARC 400 to the AUTOCON III 400 with respect to technological characteristics, principles of operation and performance. This forms the basis for the determination of substantial equivalence to the predicate device.

Table 5A – Comparison of Characteristics

Attribute	**Subject Device** **ARC 400**	**Predicate Device** **AUTOCON III 400**
510(k) Number	K193591	K171717
Manufacturer	BOWA-electronic GmbH & Co. KG	KARL STORZ Endoscopy
Product Code	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Mechanism of Action	The device generates high frequency current 350 kHz / 1 MHz	The device generates high frequency current 350 kHz / 1 MHz
System voltage	100 – 127 V	100 – 127 V
Monopolar Cutting Modes (12)		
Max. Power	400 W (at 200 Ω)	400 W (at 200 Ω)
Output Frequency	350 kHz	350 kHz
Max. Voltage Output	1600 Vp	1600 Vp
Crest Factor	1.5, 3.5	1.5, 3.5

Attribute	Subject Device ARC 400	Predicate Device AUTOCON III 400
Wave Forms	Sinusoidal Constant Sinusoidal Modulated Sinusoidal Alternating Cut/Coag/Pause Phases	Sinusoidal Constant Sinusoidal Modulated Sinusoidal Alternating Cut/Coag/Pause Phases
Monopolar Coagulation Modes (9)		
Max. Power	250W (at 500 Ω)	250W (at 500 Ω)
Output Frequency	350 kHz	350 kHz
Max. Voltage Output	5000 Vp	5000 Vp
Crest Factor	1.6 – 7.4	1.6 – 7.4
Wave Forms	Sinusoidal Constant Sinusoidal Modulated Pulse Modulated	Sinusoidal Constant Sinusoidal Modulated Pulse Modulated
Bipolar Cutting Modes (4)		
Max. Power	400 W (at 75 Ω)	400 W (at 75 Ω)
Output Frequency	350 kHz	350 kHz
Max. Voltage Output	500 Vp	500 Vp
Crest Factor	1.5 – 1.6	1.5 – 1.6
Wave Forms	Sinusoidal Constant	Sinusoidal Constant
Bipolar Coagulation Modes (9)		
Max. Power	350 W (at 25 Ω)	350 W (at 25 Ω)
Output Frequency	350 kHz	350 kHz
Max. Voltage Output	550 Vp	550 Vp
Crest Factor	1.5 – 3.8	1.5 – 3.8
Wave Forms	Sinusoidal Constant Pulse Modulated	Sinusoidal Constant Pulse Modulated

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of the ARC 400 and to show substantial equivalence to the predicate device (AUTOCON III 400), BOWA completed successfully the following non-clinical performance tests:

Electrical safety testing	ES 60601-1 / 19-4
Electromagnetic Compatibility testing	IEC 60601-1-2 / 19-8
Particular requirements for the basic safety and essential performance of high frequency surgical equipment	IEC 60601-2-2 / 6-389
Performance testing	Applicable parts of FDA Guidance Document "*Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*" May 2016
Usability testing	IEC 62366 / 5-114

The results confirm that the design inputs and performance specifications for the ARC 400 are met. The device passed the testing in accordance with FDA and international recognized standards, national standards, and internal requirements as shown above, supporting its safety and effectiveness, and its substantial equivalence to the AUTOCON III 400.

10. Statement of Substantial Equivalence

The ARC 400 has the same intended use as the AUTOCON III 400, and the same technological characteristics. The non-clinical test results, such as performance data, software data, electrical safety and electromagnetic compatibility data have demonstrated the ARC 400 is as safe and effective as the predicate device. Therefore it is concluded, that the ARC 400 fulfills the requirements of a substantially equivalent device and that no new questions of safety and effectiveness were raised.