March 22, 2023

Richard Wolf Medical Instruments Corporation
Mike Mcandrew
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K230194
Trade/Device Name: HF Surgery Generator 400KHZ
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, 2023
Received: January 24, 2023

Dear Mike Mcandrew:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.22 15:31:45 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
To be determined

Device Name
HF SURGERY GENERATOR 400KHZ

Indications for Use *(Describe)*
The product is used for generating high frequency electrical current for cutting and coagulating tissue electrosurgically.

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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# 5 510(k) Summary

## I Submitter

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Contact Person, Mike McAndrew, US Head of Regulatory – QA/QC
Date Prepared: March 21, 2023

**Legal Manufacturer**
Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

## II Device

*Table 5-1: Device classification*

| Brand name | Trade name | Model Number | Product classification name | Regulation Number and Name | Product Code | Device Class | Review Panel |
|---|---|---|---|---|---|---|---|
| 2260 | HF SURGERY GENERATOR 400KHZ | 2260003 | Electrosurgical, Cutting & Coagulation & Accessories | 878.4400 Electrosurgical cutting and coagulation device and accessories | GEI | Class II | General and Plastic Surgery |
| N/A | FOOTSWITCH 2 PEDALS L 5M | 2260021 | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| N/A | HF CONNECTION CABLE BIPO L 3M | 8108233 | | | | | |
| N/A | HF CONNECTION CABLE BIPO L 5M | 8108253 | | | | | |

## III Predicate Device

Trade name of Predicate Device: ARC 400

510(k) Number: K193591

Regulatory Class: Class II

Product Code: GEI

Manufacturer: BOWA-Electronics GmbH & Co. KG

The predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

## 5.1 Subject Device Description

### 5.1.1 Device Identification

*Table 5-2: Device identification*

| Brand name | Model Number | Trade name | Package unit |
|---|---|---|---|
| 2260 | 2260003 | HF SURGERY GENERATOR 400KHZ | 1 |
| N/A | 2260021 | FOOTSWITCH 2 PEDALS L 5M | 1 |
| N/A | 8108233 | HF CONNECTION CABLE BIPO L 3M | 1 |
| N/A | 8108253 | HF CONNECTION CABLE BIPO L 5M | 1 |

### 5.1.2 Device characteristics

**Delivered sterile / non-sterile**

The HF SURGERY GENERATOR 400KHZ is delivered non-sterile and sterilization is not required.

**Single use / reusable**

The devices are reusable and do require cleaning and reprocessing during their use-life, i.e., users are required to clean and disinfect the device before every application and before returning for repairs. Methods of cleaning and reprocessing are detailed in the Instruction for Use.

**Software**

The HF SURGERY GENERATOR 400KHZ contains software.

The software is classified as a **Major Level of Concern**.

**Materials with patient contact**

The HF SURGERY GENERATOR 400KHZ is not intended to contact the patient directly or indirectly.

### 5.1.3 Brief written description of the Device

The HF SURGERY GENERATOR 400KHZ is used for electrosurgical cutting and coagulation of living human tissue. For this purpose, electrical energy from the power supply network is transformed into high frequency current which allows this surgical property. The device offers a multitude of different profiled current forms which are optimized for the different surgical requirements. It is equipped for monopolar and bipolar cutting and coagulation in micro- and macrosurgical operations.

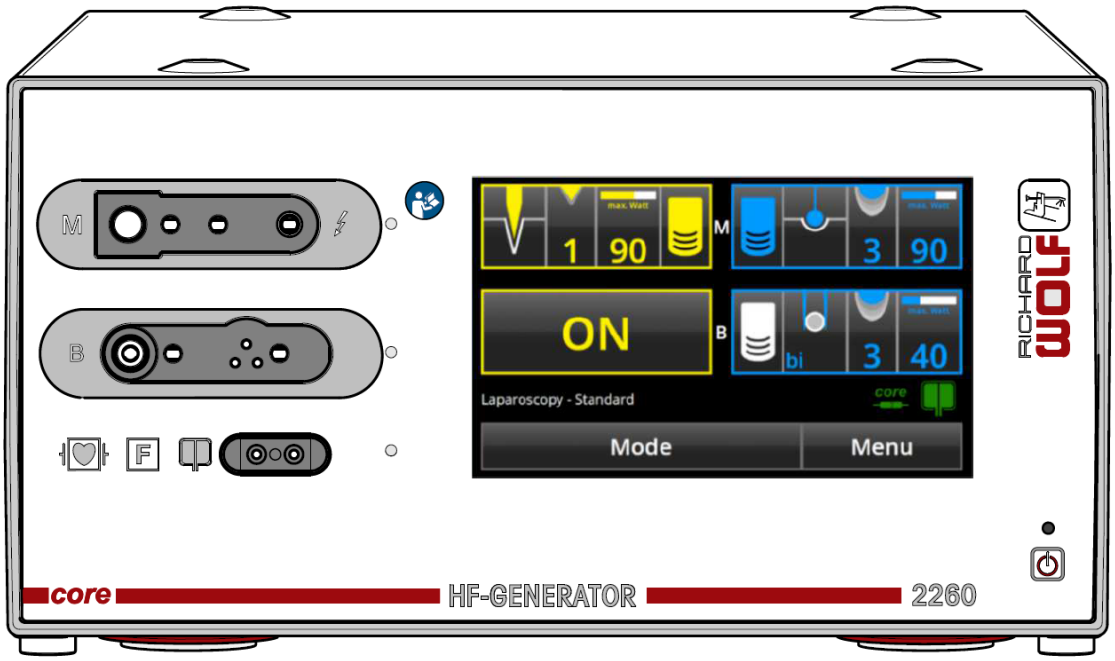


*Figure 05-1: Richard Wolf HF SURGERY GENERATOR 400KHZ*

### 5.1.4 Materials of Use

The HF SURGERY GENERATOR 400KHZ consists of a metal housing which does not have any patient contact.

## 5.2 Indications for Use

**Statement**

The product is used for generating high frequency electrical current for cutting and coagulating tissue electrosurgically.

**User**

This product is exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately instructed persons.

**Patient population**

The product is intended for adult patients.

The patient group intended for the application of the medical product herein described is not limited with regard to ethnicity, gender, body height and weight. Before use, the attending physician must make sure that the product in view of its dimensions or settings can be used safely in the patient.

**Explanation on differences to the predicate device**

In comparison to the predicate device, the usage of the subject device is further restricted to adults. However, the full indication of use for the subject device is covered by the predicate device and reducing the scope does not lead to new questions regarding safety and effectiveness.

## 5.3 Comparison of Technological Characteristics with the Predicate Device

### 5.3.1 Overview Table

*Table 5-3: Comparison of technical characteristics*

| Item | Subject device | Predicate devices | Comparison |
|---|---|---|---|
| **General information** | | | |
| Product name | HF SURGERY GENERATOR 400KHZ | ARC 400 Electrosurgical Unit | N/A |
| Brand name | 2260 | N/A | N/A |
| Type No. | 2260003 | 900400 | N/A |
| 510(k) number | TBD / subject device | K193591 | N/A |
| Manufacturer | Richard Wolf GmbH | BOWA-electronics GmbH & Co. KG | N/A |
| Product Code | GEI | GEI | Same |
| Regulation Number | 878.4400 | 878.4400 | Same |
| Indications for Use | The product is used for generating high frequency electrical current for cutting and coagulating tissue electrosurgically. | The HF device is intended exclusively for the generation of electrical power for monopolar and bipolar cutting and coagulation on tissue structures in surgical operations. | Equivalent |
| Contraindications | Contraindications directly related to the product are presently unknown. If medical contraindications for the mentioned indications are known, the use of the products is not permitted.<br>On the basis of the patient's general condition the doctor in charge must decide whether or not the planned use is possible. | Do not use the HF device if, in the opinion of an experienced physician or according to current professional literature, such use would endanger the patient, due for example to the general condition of the patient, or if other contraindications are present. | Equivalent |
| Prescription/ over-the-counter-use | RX only | RX only | Same |

| Item | Subject device | Predicate devices | Comparison |
|---|---|---|---|
| Sterile/Non-sterile device | Non-sterile device | Non-sterile device | Same |
| Single use/ Reusable | Reusable device | Reusable device | Same |
| Sterilization method | Non-sterile device | Non-sterile device | Same |
| Reprocessing | Cleaning and disinfection solution/wipes for low level should be based on alcohol. Examples for suitable substances for cleaning and disinfection of surfaces:<br>• Propanol<br>• Ethanol<br>• Didecyldimethylammoniumchloride<br>• Dimethylbenzylammoniumchloride | Apply the cleaning agent and disinfectant.<br>Wipe down the HF device only with cleaning agents and disinfectants that are approved in the country of use for surface cleaning. | Equivalent |
| Maintenance intervals | 12 months | 12 months | Same |
| Operating Condition | Ambient temperature +10 °C to +40 °C<br>Relative humidity 30% to 75% (non-condensing)<br>Atmospheric pressure 700 hPa to 1060 hPa | Temperature: +10 °C to +40 °C<br>Relative humidity: 30 to 75%, non-condensing<br>Atmospheric pressure: 700 to 1600 hPa<br>Operating altitude (max.) 4000 m above sea level | Equivalent |
| Storage and Transport Conditions | Ambient temperature -20 °C to +60 °C<br>Relative humidity 10% to 90% (non-condensing)<br>Atmospheric pressure 700 hPa to 1060 hPa | Temperature: -20 °C to +50 °C<br>Relative humidity 0 to 75 %, non-condensing<br>Atmospheric pressure: 500 to 1600 hPa | Equivalent |
| **Operational modes / settings** | | | |
| Mode: Monopolar cutting | | | |
| Modes | 12 | 12 | Same |
| Max. Power | 400 W (at 500 Ω) | 400 W (at 200 Ω) | Same |
| Output Frequency | 403 - 500 kHz | 350 kHz | Different |
| Max. Voltage Output | 3150 Vp | 1600 Vp | Different |
| Crest Factor | 1.4 - 4.4 | 1.5, 3.5 | Different |
| Wave Forms | Sinusoidal Constant<br>Sinusoidal Modulated<br>Sinusoidal Alternating | Sinusoidal Constant<br>Sinusoidal Modulated<br>Sinusoidal Alternating<br>Cut/Coag/Pause Phases | Equivalent |
| Mode: Monopolar coagulation | | | |
| Modes | 15 | 9 | Different |
| Max. Power | 200 W (at 350 Ω) | 250 W (at 500 Ω) | Different |
| Output Frequency | 375 - 500 kHz | 350 kHz | Different |
| Max. Voltage Output | 5000 Vp | 5000 Vp | Equivalent |
| Crest Factor | 1.4 - 7.6 | 1.6 - 7.4 | Different |
| Wave Forms | Sinusoidal Constant<br>Sinusoidal Modulated<br>Pulse Modulated | Sinusoidal Constant<br>Sinusoidal Modulated<br>Pulse Modulated | Same |
| Mode: Bipolar cutting | | | |

| Item | Subject device | Predicate devices | Comparison |
|---|---|---|---|
| Modes | 8 | 4 | Different |
| Max. Power | 300 W (at 100 Ω) | 400W (at 75 Ω) | Different |
| Output Frequency | 355 - 381 kHz | 350 kHz | Different |
| Max. Voltage Output | 750 Vp | 500 Vp | Different |
| Crest Factor | 1.4 - 2.3 | 1.5 - 1.6 | Different |
| Wave Forms | Sinusoidal Constant | Sinusoidal Constant | Same |
| Mode: Bipolar coagulation | | | |
| Modes | 9 | 9 | Equivalent |
| Max. Power | 250 W (at 75 Ω) | 350 W (at 25 Ω) | Different |
| Output Frequency | 338 - 381 kHz | 350 kHz | Different |
| Max. Voltage Output | 425 Vp | 550 Vp | Different |
| Crest Factor | 1.4 - 1.7 | 1.5 - 3.8 | Different |
| Wave Forms | Sinusoidal Constant Pulse Modulated | Sinusoidal Constant Pulse Modulated | Same |
| **Technological characteristics** | | | |
| Standard compliance | IEC 60601-1:2005 (19-4)<br>IEC 60601-1-2:2014 (19-8)<br>IEC 60601-2-2:2017 (6-389) | IEC 60601-1: 2005 (19-4)<br>IEC 60601-1-2: 2014 (19-8)<br>IEC 60601-2-2:2017 (6-389) | Same |
| Voltage [V] | 100-240 V | 230 V | Equivalent |
| Frequency [Hz] | 50/60 Hz | 50/60 Hz | Same |
| Power consumption [VA] / Current rating [A] | 45 without HF output<br>650 at max. output power | 85 power consumption in standby mode<br>975 maximum power consumption with 300 W HF output power | Equivalent |
| Protection class to EN/IEC 60601-1;<br>(UL 2601-1/CSA C22.2 No.601.1 – for USA) | I | I | Same |
| Protection against electric shock | CF applied part, defibrillator-proof | CF | Same |
| Degree of protection against liquids | IPX0 | IP 21 | Equivalent |
| Weight [kg] | 10.2 kg (22.4 lbs) | approx. 12.5 kg | Different |
| Dimensions | 300 x 160 x 402 mm | 430 x 180 x 475 mm | Different |
| Material | Metal & plastics | Metal & plastics | Equivalent |
| Single-Use | No | No | Same |
| Light Source | No | No | Same |
| Battery Operated | No | No | Same |
| AC Powered | Yes | Yes | Same |
| Software version | 1.4.3 | 1.0.0.6.17.9 | Different |
| USB Port | Yes | Yes | Same |
| Potential equalization connector | Yes | Yes | Same |
| LAN (Ethernet) Network Connector (RJ45) | Yes | Yes | Same |

| Item | Subject device | Predicate devices | Comparison |
|---|---|---|---|
| Foot switch socket connector | Yes | Yes | Same |
| Control elements / user interface | Touchscreen | Touchscreen | Same |
| **Materials with patient contact** | | | |
| Materials with direct patient contact | N/A - no materials with direct patient contact | N/A - no materials with direct patient contact | Same |
| Materials with indirect patient contact | N/A - no materials with indirect patient contact | N/A - no materials with indirect patient contact | Same |
| **Instruction for use** | | | |
| Version | GA-A339 / en / US / V0.6 | 900-400_IFU_V1.0.0.6.17.9_20140-S2-20130604-EN | Different |

### 5.3.2 Discussion

The subject device and the predicate device share the same fundamental technology. They both convert electrical energy from the grid into a high-frequency current which provides the surgical property. For that purpose, monopolar and bipolar high frequency current modes were provided to the corresponding socket module. The fundamental frequencies of about 400 kHz provided by the subject and the predicate device are comparable and substantial equivalent. Both generators feature a maximum power output of 400 W.

The general and technical characteristics that differ between the predicate and the subject device are differences in PCB layouts, software including the graphical user interface, number of output sockets and other technical characteristics such as power consumption and weight, dimensions. These differences do not question safety and effectiveness of the subject devices, several performance tests were performed, such as:

a. Validation of the electromagnetic compatibility and electrical safety (Section 17 - Electromagnetic Compatibility and Electrical Safety)
b. Validation of the performance on tissue (Section 19 – Performing Testing Animal)
c. Validation of the performance based on waveform comparison and the tissue study (Section 18 – Performance Testing Bench)
d. Performance testing due to the different software functions, the change in power consumption, cooling method, and the “Dialog” function (Section 18 – Performance Testing Bench)
e. Transportation validation (Section 18 - Performance Testing Bench)

## 5.4 Performance Testing

### 5.4.1 Sterilization

N/A

### 5.4.2 Biocompatibility

N/A

### 5.4.3 Electromagnetic Compatibility and Electrical Safety

The predicate device and the device covered by this registration are classified in protection class I according to 60601-1. They both fulfil the electrical safety requirements of IEC 60601-1, IEC 60601-2-2 and IEC 60601-1-2. Based on that, the devices are considered to be comparable in terms of electromagnetic compatibility and electrical safety.

### 5.4.4 Performance and Operational testing

The efficacy and safety of the HF SURGERY GENERATOR 400KHZ is documented by the verification and validation testing which confirms that the product meets all the requirements and specifications for overall design, basic safety, essential performance, and that the design inputs and specifications are met.

## 5.5 Conclusions

The HF SURGERY GENERATOR 400KHZ has the same intended use and field of application as the legally marketed predicate device named in this submission.

The same performance tests were concluded for the subject device as for the predicate device. Therefore, no comparison testing was performed. Non-clinical performance testing, including Electromagnetic Compatibility, Electrical Safety, and Software Verification and Validation, demonstrated that the safety and performance of the device is equivalent to the predicate device. Differences in characteristics described in Section 12.2 do not raise any new questions regarding the safety and effectiveness of the HF SURGERY GENERATOR 400KHZ compared to the predicate device.

The HF SURGERY GENERATOR 400KHZ is substantially equivalent to the legally marketed predicate device ARC 400 (K193591).