August 25, 2023

Kirwan Surgical Products LLC
Mr. Matthew Prario
Regulatory Affairs Manager
180 Enterprise Drive
Marshfield, Massachusetts 02050

Re: K231872
Trade/Device Name: Polaris Bipolar Electrosurgical Generator System

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 23, 2023
Received: June 26, 2023

Dear Mr. Prario:

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,

Francisco Delgado -S
2023.08.25 09:31:53 -04'00'

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231872

Device Name
Polaris Bipolar Electrosurgical Generator System

Indications for Use *(Describe)*
General-purpose solid-state bipolar generator used to supply High Frequency currents via electrosurgical handpieces for the function of cutting or coagulating soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered.

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."

K231872
510(k) Summary
Polaris™ Bipolar Electrosurgical Generator System

A. Sponsor

Kirwan Surgical Products LLC
180 Enterprise Drive
Marshfield, MA 02050

B. Contact

Mr. Matthew R. Prario
Regulatory Affairs Manager
Phone: 339-832-1743
Email: mprario@ksp.com

C. Device Name

Trade Name:	Polaris Bipolar Electrosurgical Generator System
Common/Usual Name:	Electrical Surgical Unit (ESU) / Bipolar Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Product Code:	GEI - 21 CFR §878.4400

D. Predicate Device(s)

Trade Name:	Aura 70-Watt Bipolar Electrosurgical Generator
Common/Usual Name:	Electrical Surgical Unit (ESU) / Bipolar Electrosurgical Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI
Predicate 510(k)	K052203 (substantial equivalence date October 20, 2005)
Reference 510 (k)s	Karl Storz (K123956)

E. Device Description

The proposed Polaris™ Bipolar Electrosurgical Generator System includes a Generator as the main console, a Footswitch, an Irrigation Module, and a Light Source Module. The Generator contains a single bipolar channel for delivery with an electrode applying the energy to the patient. The Irrigation Module connects to tubing that allows fluid to be delivered to the surgical site to allow for clearing of debris from the surgical field. The Light Source Module connects to an optical fiber that supplies illumination to the surgical site to assist with surgeon visualization. The Footswitch is used to control the delivery of RF energy to the patient with one switch for Coagulate and one for Cut power. The Generator includes 4

Module ports for controlling and powering the Modules. The Modules each have built in cords to connect to these ports on the Generator. The Modules mount to the top of the Generator using a locking rail system so that they will not accidentally come loose during use. The Irrigation Module includes an IV pole that attaches to the Generator to support a saline bag that supplies the irrigation fluid.

F. Indications for Use

The proposed Polaris™ Bipolar Electrosurgical Generator has the following Indications for Use:

- *The Polaris™ Bipolar Electrosurgical Generator is a general-purpose solid-state bipolar generator used to supply High Frequency currents via electrosurgical handpieces for the function of cutting or coagulating soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered.*

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed Polaris™ Bipolar Electrosurgical Generator is substantially equivalent to the Aura 70-watt Bipolar Electrosurgical Generator. When compared to the predicate, the proposed Polaris™ Bipolar Electrosurgical Generator have similar materials, design, components, fundamental technology, and operating principles and the same indications for use. The modifications from the predicate device include: power and control connections for modules, capacitive touch screen over a resistive touch screen, dual waveform generation, expanded User Interface, and downloadable system diagnostic logs. These similarities and differences are illustrated in the following table.

Comparison of Proposed Polaris™ Bipolar Electrosurgical Generator And Predicate Aura 70-Watt Bipolar Electrosurgical Generator		
Characteristic(s)	**Proposed Device:** Polaris™ Bipolar Electrosurgical Generator **(K231872)**	**Predicate Device:** Aura 70-watt Bipolar Electrosurgical Generator **(K052203)**
Indications for Use	General-purpose solid-state bipolar generator used to supply High Frequency currents via electrosurgical handpieces for the function of cutting or coagulating soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered.	General-purpose solid-state bipolar generator to supply RF signal to electrosurgical handpieces used on soft body tissue where a wide range of tissue types, patient conditions, and load impedances are encountered. Where applicable a peristatic irrigation pump controls flow rate individually or simultaneously while coagulating.
Hardware		
Output	Bipolar	Bipolar
Number of Outputs	One	One
Physical Dimensions (HxWxD) (cm)	38.1 x 19.2 x 38.4	17.8 x 29.2 x 31.8
Weight in lbs.	14.64	15
Maximum Output Voltage (V_{rms})	160	200
Rated Load (ohms)	150	200
Frequency Output Range (kHz)	465.1	512
Power Outage Range (W)	0-80 (CUT Waveform) 0-60 (COAG Waveform)	0-70
Housing Material	Anodized aluminum, Teal	Anodized Aluminum, Grey

Comparison of Proposed Polaris™ Bipolar Electrosurgical Generator And Predicate Aura 70-Watt Bipolar Electrosurgical Generator		
Characteristic(s)	**Proposed Device:** Polaris™ Bipolar Electrosurgical Generator **(K231872)**	**Predicate Device:** Aura 70-watt Bipolar Electrosurgical Generator **(K052203)**
Indications for Use	General-purpose solid-state bipolar generator used to supply High Frequency currents via electrosurgical handpieces for the function of cutting or coagulating soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered.	General-purpose solid-state bipolar generator to supply RF signal to electrosurgical handpieces used on soft body tissue where a wide range of tissue types, patient conditions, and load impedances are encountered. Where applicable a peristatic irrigation pump controls flow rate individually or simultaneously while coagulating.
Electrical Input	100-240V_{rms}, 50/60Hz	90-240VAC, 50/60Hz
Irrigating Pump	Polaris Irrigation Module	Maxon 40mm Peristaltic Pump
Max Irrigation Flow Rate (mL/min)	25	50
Light Source	Polaris Light Source Module	Not Present
Screen	Capacitive Touch Screen	Kyocera Resistive Touch Screen
Software/UI		
CPU Software	Proprietary to RBC Medical Innovations	Merisc Custom
Control Board Software	Proprietary to RBC Medical Innovations	Supplied by IBBAB
Amplifier Software	Proprietary to RBC Medical Innovations	Proprietary to IBBAB
Error History	Yes	Not present
Service Mode	Yes	Not present
Downloadable System Logs	Yes	Not present
Output time Tracking	Yes	Yes
Available Output Units	Max-Watts/ESU	Watts/ESU
Accessories		
Foot Pedal	Dual Simple Switches	Simple Switch
Bipolar Surgical Tools	*Yes*	Yes
Miscellaneous		
Patient Contact	No	No
Sterilization Method	Not Applicable	Not Applicable
Preventative Maintenance	Yearly Function Checks	Yearly Function Checks
Changing b/w Watts and ESU	In Settings Menu via UX	Internal Hardware Jumper

H. Performance Data

Thermal Effects on Tissue

In accordance with the FDA Guidance on 510(k) Submissions for Electrosurgical Devices for General Surgery, a comparative tissue coagulation evaluation was performed between the proposed device and the predicate (Engineering Report E070723-1).

Test Scope: The testing was performed using one Aura Bipolar Electrosurgical Generator and one Polaris Bipolar Electrosurgical Generator. Both units were tested with the same bipolar forceps sample part on the same tissue samples and were operated at the same output settings.

3 Types of Sample Test Tissue (Bovine):

- Liver Tissue
- Kidney Tissue
- Muscle Tissue

Acceptance Criteria: To be considered acceptable, the results of this testing will demonstrate that the coagulation sites of both generators are substantially equivalent when set to the same output settings. This includes the physical measurement of the coagulation site, as well as the relative temperature increase while bipolar output was active. All physical measurements and temperature changes should fit within an acceptable range utilizing a ± 20% tolerance.

Test Conclusion: Based on the results and rationale presented above, both devices were successful in achieving a similar, desired coagulation effect on similar tissue, and both heated tissue at similar rates to a similar peak temperature. It is the conclusion of this Engineering Report that the Polaris Bipolar Electrosurgical Generator (K231872) is substantially equivalent to its predicate, Aura Bipolar Generator (K052203), when operated by the intended user of the device.

Waveform Testing

In accordance with the FDA Guidance on 510(k) Submissions for Electrosurgical Devices for General Surgery, a comparative waveform test was performed between the proposed device and the predicate (Engineering Report E071123-1).

Test Scope: The evaluation and testing were performed on one production Aura 70W Bipolar Electrosurgical Generator, model number 28-2600, assembled using standard manufacturing procedures and one production Polaris Bipolar Electrosurgical Generator model number 29-1000, assembled using standard manufacturing procedures. Both systems were set to a 20-Watt output with a 100Ω load to establish frequency and voltage RMS differences.

Test Results: Capturing the absolute values from a sine wave of an RF generator may produce a 10% variation in value depending on how long the signal is maintained and where in the cycle the data was extrapolated. The values presented in report E071123-1 were obtained as an average of the signal over a 3 second time period.

Test Conclusion: Although the values are slightly different, the outputs are well within the 20% output variation between like systems. Based on the results presented in report E071123-1, Kirwan Surgical

Products LLC determines that the output waveform of the Polaris Bipolar Electrosurgical Generator is substantially equivalent to the waveform produced by the predicate Aura 70W Bipolar Electrosurgical Generator, when they are operated with similar output settings.

Electrical Safety & Electromagnetic Compatibility Tests

Electrical safety and electromagnetic compatibility (EMC) Electrical safety and EMC testing were conducted on the Polaris™ Bipolar Generator System, consisting of the main Polaris™ Bipolar Electrosurgical Generator, Dual Footswitch, Polaris™ Irrigation Module, and Polaris™ Light Source Module.

The system has passed the following tests and complies with the associated standards;

- Electrostatic Discharge Test (IEC 60601-1-2)
- Radiated Immunity Test (IEC 61000-4-3)
- Electrical Fast Transient/Burst Test (IEC 61000-4-4)
- Surge Test (IEC 61000-4-5)
- Conducted Immunity Test (IEC 61000-4-6)
- Power Frequency Magnetic Field Test (IEC 61000-4-8)
- Voltage Dips & Interruptions Test (IEC 60601-1-2)
- Radiated Emissions Test (CISPR 11 & FCC CFR 47, Part 15, subpart B:2017)
- Conducted Emissions Test (CISPR 11 & FCC CFR 47, Part 15, subpart B:2017)
- Harmonic & Flicker Test (IEC 61000-3-2 & IEC 61000-3-3)
- Exposure to Radio Frequency Identification Readers Test (AIM 7351731)
- Immunity to Known Sources of EMI Test (FDA Guidance – Immunity to exposure to known sources of EMI)

Electrical Safety Testing Clause by Clause Compliance to IEC 60601-1, IEC 60601-1-6, IEC 60601-2-2, and IEC 62471

Software Verification & Validation testing

Software Verification and Validation Testing Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator. All software verification & validation activities are outlined in the Kirwan Polaris Software Development Plan (document number 100-00068-004).

Human Factors Testing

The purpose of the Polaris™ Bipolar Generator System Human Factors testing was to Evaluate if the User Interface enables all User Profiles to safely operate the Polaris System. Evaluate if the User Interface enables all User Profiles to effectively and efficiently operate the Polaris System. Identify and document any Abnormal Use's, unknown Use Errors, and difficult to complete tasks. Determine roots causes for all Use Errors and evaluate their Risk acceptability. The User Interface for the Polaris System was designed to be intuitive enough for a User to be able to setup and operate the system without need for KSP training or in-service of any kind.

The first user profile was to be populated by Surgeons & Surgical Physician Assistants, and the second was to be populated by Perioperative Nurses and Biomedical Equipment Technicians.

27 Tasks that were identified as functions necessary for a User to perform to effectively use all the capabilities of the Polaris System. All Users were able to fulfill these functions during testing. The few Users who did not score perfect on the final test were due to misunderstanding of the test instructions or due to other circumstances outside their control. There were no noted issues of user error during any of the final testing.

19 Critical Tasks that were identified to safely operate the Polaris system and avoid Hazardous situations with a Severity level of 3 or higher (a situation that can result in injury that require medical intervention or worse). All Users were able to perform the Critical Tasks, and there were no recorded instances of Use Error or Abnormal Use that would result in a Hazardous Situation with a severity level of 3.

In conclusion, users whose background is consistent with either of the utilized User Profiles will be able to operate the Polaris safely, effectively, and without the need for formal training.

I. Conclusion

Based upon successful results of testing and responses to questions posed within FDA's 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent to the identified predicate device. Although there are some minor differences between the proposed Polaris Bipolar Electrosurgical Generator System and the predicate Aura 70W Bipolar Electrosurgical Generator, these differences do not raise new or different questions of safety and efficacy.