April 25, 2024

Single Pass, Inc.
Bill Colone
CEO
105 North Pointe Drive Suite B
Lake Forest, California 92630

Re: K232805
Trade/Device Name: Kronos Electrocautery Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 5, 2023
Received: March 17, 2024

Dear Bill Colone:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.04.25 09:23:25 -04'00'

Mark Trumbore, Ph.D.
Acting 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)*
K232805

Device Name
Kronos Electrocautery Device

Indications for Use *(Describe)*
The Kronos Electrocautery Device is indicated to be used as a tool to achieve hemostasis through coagulation for liver, kidney, and lung soft tissue.

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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Kronos Electrocautery Device
510(k) Summary

This 510(k) summary for Kronos Electrocautery Device is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]*, dated 28 July, 2014.

SUBMITTER [807.92(a)(1)]

Single Pass, Inc.
105 North Pointe Drive, Suite B
Lake Forest, CA 92630

Contact Person:	Bill Colone 105 North Pointe Drive, Suite B Lake Forest, CA 92630 United States
Telephone:	602-618-3377
E-mail:	bcolone@singlepass.co
Date prepared:	September 05, 2023 (revised February 29, 2024)

DEVICE [807.92(a)(2)]

Name of Device:	Kronos Electrocautery Device
Common or Usual Name:	Unit, Cautery, Thermal, Battery-Powered
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Product Code:	GEI
Regulatory Class:	Class II
Submission Type:	Traditional 510(k)
Regulation Number:	21 C.F.R. 878.4400
Reviewing Product Branch:	General and Plastic Surgery Device (Office of Device Evaluation, CDRH)

PREDICATE DEVICE [807.92(a)(3)]

Bovie Cautery Device (K121441)

DEVICE DESCRIPTION [807.92(a)(4)]

The Kronos Electrocautery Device is a single-use, disposable and battery-operated electrocautery device utilized to control bleeding post-biopsy procedure of solid organs (i.e., liver, kidney, lungs, etc.). The Kronos electrosurgical device consists of:

- a power supply: Two AA batteries

- a Stainless Steel (SS) distal probe with a rounded heated tip that is connected to the handle to cauterize targeted areas of tissue. The tip is heated (75 °C – 100 °C) via electrical current through a coiled wire. The temperature of the distal tip is controlled with a thermistor while the temperature of the tip is distributed with a thermal conductive epoxy.

- The ergonomic handle includes an on/off switch and a push button to activate the heated tip.

Kronos Electrocautery Device is available in two models, K10 and K15. K10 model is compatible with 10cm guide needle whereas K15 is compatible with 15cm guide needle.

INDICATIONS FOR USE [807.92(a)(5)]

The Kronos Electrocautery Device is indicated to be used as a tool to achieve hemostasis through coagulation for liver, kidney, and lung soft tissue.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The technological characteristics of the Kronos Electrocautery Device are substantial equivalent to the technological characteristics of the Bovie Cautery Device previously cleared (K121441). Substantial equivalence is determined based on the following similarities:

- Same intended use
- Similar principles of operation
- Similar design, materials of construction, fundamental scientific technology

Table 4-1 comprises the comparison between Kronos Electrocautery Device (Subject Device) and Bovie Cautery Device (Predicate Device, K121441).

Table 4-1: Predicate Device vs. Subject Device Comparison Table

Feature	Bovie Cautery Device [PREDICATE DEVICE K121441]	Kronos Electrocautery Device [SUBJECT DEVICE]
Product Code	GEI	Same
Regulatory Class	Class II	Same
Regulation Number	21 CFR 878.4400	Same
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Same
Generic Name	Battery Operated Cautery; Cauterizer	Same
Indications for Use Statement	Bovie Cautery Devices are used for stopping small bleeders in hemostasis and other similar uses.	The Kronos Electrocautery Device is indicated to be used as a tool to achieve hemostasis through coagulation for soft tissues such as liver, kidney, spleen, lymph nodes and various soft tissue lesions.
Intended Use	Used for stopping bleeding	Used for stopping bleeding
Sterility	Single Use; Sterilized by Ethylene Oxide; Sterility Assurance Level of 10^{-6}	Single Use; Sterilized by Ethylene Oxide; Sterility Assurance Level of 10^{-6}
Materials	Patient contacting tips constructed of Nichrome 80 and Kanthal A-1. Cautery handles constructed of Acrylonitrile Butadiene Styrene (ABS). Cautery tip tubes are embedded in the handle.	Patient contacting tip is made of 316 stainless steel. Patient contacting probe is made of 304 stainless steel. The handle assembly is made of ABS material.
Energy Source	Device is powered by one or two 1.5 volt alkaline batteries	Device is powered by two (2) 1.5 volt alkaline batteries

Feature	Bovie Cautery Device [PREDICATE DEVICE K121441]	Kronos Electrocautery Device [SUBJECT DEVICE]
Principle of Operation	The device is activated by pressing the green button on the cautery body. Once the button is pressed, an internal circuit is completed that directs power from an internal battery to the cautery tip which in turn heats. The heated tip is introduced to the surgical site and the heat vaporizes the water component in blood/tissue, causing a clot that halts the bleeding.	The principle of operation involves heating of the device probe tip by the use of an electrical current. The heated probe tip is applied directly to the target tissue area of treatment to control bleeding.
Method of Supply	Sterile, Single Use	Same
Configuration	Not Listed	KU10 KU15
Probe Outer Diameter	Not Listed	0.040”
Working Length	Not Listed	KU10: 17cm KU15: 22cm
Guide Needle Compatibility	Not Listed	K10: 10cm guide needle K15: 15cm guide needle

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing, Animal Testing, US and OUS Clinical Studies: Results of the performance bench testing, animal testing (usability evaluation and thermal effects histology), US Clinical Studies and OUS Clinical Studies (**Table 4-2**) indicate that Kronos Electrocautery Device (Subject Device) meets established performance requirements and is substantially equivalent for its intended use.

Table 4-2: Performance Bench Testing and Animal Testing Summary

Performance Bench Testing		
Tests	**Test Method Summary**	**Results**
Physical Attribute	Inspected dimensions for distal tip, working length, outer diameter.	All test samples passed testing.
Surface Contamination	A microscope was used to inspect the device surface for the presence of particulates.	All test samples passed testing
Time-Temperature Characterization Study	A calibrated thermometer was used to measure the temperature of device while the device was turned on and submerged under water.	All test samples passed testing.
Tensile Test	Measured the distal tip tensile force using an Instron tensile tester.	All test samples passed testing.
Performance Animal Testing		
Animal Testing (GLP)	Animal testing is to evaluate the *in vivo* performance of the device in an acute swine model. All Usability Evaluation Ratings scored ≥3 (acceptable) for the following: - Device Condition (Visual Inspection) - Maneuverability to Target Tissue - Device Performance (Blood - Control) - Compatibility with Guide Needle - Withdrawal Force were assessed.	All test samples passed testing.

Histopathological Assessment	The thermal effects of the subject device against the predicate device in porcine tissue explants using histopathologic analysis were performed. The subject devices and the predicate device were tested on four porcine tissue types including liver, lung, kidney, and skeletal muscle. The surface and depth (up to 1.6 cm deep into tissues) of each tissue type was treated at triplicated sites for 10 seconds. An additional 10 seconds was added while removing the active probe from deep treatment sites. Control samples were prepared by penetrating the tissues with the inactive probe without cauterizing the tissues. The treated tissues were evaluated histopathologically via light microscopy, and the dimension of the cauterized areas were measured.	There were no significant differences between the thermal damage induced by subject device as compared to the predicate device. The subject device is equivalent in safety and efficacy of the predicate device. The intensity of the thermal damage and structure of cauterized areas were similar. Mild cellular damage along with tinctorial changes were found at the site of treatments in all tissues. There was no major thermal damage beyond the active tip of the probe. The subject device induced a stronger thermal injury on the surface of the tissues with visible burn margins separating the treatment sites from the adjacent healthy tissues.

Performance US Clinical Study		
US Clinical Study	The primary objective for this study is to assess safety and performance of the Kronos Electrocautery Device for electrocautery procedures following a biopsy procedure in the liver, lung, kidney, etc. This was designed as a multicenter, prospective, non-randomized feasibility study designed to evaluate the performance of the Kronos Electrocautery Device. It was planned for up to 30 participants with the involvement of each participant lasting up to 14 days. Primary Study Outcomes: - Absence of Hematoma formation - Measure and categorize amount of blood loss from biopsy access site - Absence of the need for ultrasound examination due to observation of bleeding	All Test Samples Passed Primary and Secondary Outcomes

	Secondary Study Outcomes: - Absence of secondary reintervention - Time to hospital discharge	
Performance OUS Clinical Study		
OUS Clinical Study	The objective of this study was to verify optimal withdrawal parameters in humans to reduce and control bleeding following a biopsy procedure in solid tissue organs and to assess preliminary usability evaluations of the Kronos Electrocautery Device. This was a single-center, prospective, non-randomized feasibility study designed to evaluate the performance of the Kronos Electrocautery Device. It was designed for up to 30 participants with the involvement of each participant lasting up to 14 days. Primary Study Outcomes: - Absence of Hematoma formation - Measure and categorize amount of blood loss from biopsy access site - Absence of the need for ultrasound examination due to observation of bleeding Secondary Study Outcomes: - Absence of secondary reintervention - Time to hospital discharge	- All Test Samples Passed Primary and Secondary Outcomes

Safety Standards: Results of the safety standards testing (**Table 4-3**) indicate that the Kronos

Electrocautery Device (Subject Device) is electromagnetically compatible (EMC) and electrically safe (ES) and compatible with common environments.

Table 4-3: Safety Standards Test Summary

<table>
<tr><th>Test</th><th>Results</th><th>Conclusion</th></tr>
<tr><td>Electromagnetically Compatibility (EMC)</td><td>
<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Radiated Emissions</td><td>Complies</td></tr>
<tr><td>AC Mains Conducted Emissions</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Harmonics</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Flicker</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Electro-Static Discharge Immunity Test</td><td>Complies</td></tr>
<tr><td>Radiated, Radio Frequency, Electromagnetic Immunity</td><td>Complies</td></tr>
<tr><td>Proximity Fields from RF Wireless Communications Equipment</td><td>Complies</td></tr>
<tr><td>Electrical Fast Transient/Burst Immunity Test</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Immunity to Surges</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Conducted, Radio-Frequency, Electromagnetic Immunity Test</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Power Frequency Magnetic Field Immunity Test</td><td>Complies</td></tr>
<tr><td>Voltage Dips/Interruption Immunity Test</td><td>The EUT is battery operated. Therefore, such test is not necessary</td></tr>
<tr><td>Radiated fields in close proximity - Immunity Test</td><td>Complies</td></tr>
<tr><td>IEC 60601-1-2 Clause 5 Worksheet</td><td>Complies</td></tr>
</table>
</td><td>electromagnetically compatible</td></tr>
<tr><td>Electrical Safety (ES)</td><td>
<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>Humidity Preconditions</td><td>Pass</td></tr>
<tr><td>Accessible Parts</td><td>Pass</td></tr>
<tr><td>Leakage Current Test</td><td>Pass</td></tr>
<tr><td>Dielectric Strength Means</td><td>Pass</td></tr>
<tr><td>Ball Pressure Test</td><td>Pass</td></tr>
<tr><td>Creepage & Clearance Measurements</td><td>N/A</td></tr>
<tr><td>Excessive Temperature</td><td>Pass</td></tr>
<tr><td>Push</td><td>Pass</td></tr>
<tr><td>Drop (Hand-held and Body-worn)</td><td>Pass</td></tr>
<tr><td>Molding Stress Relief</td><td>Pass</td></tr>
</table>
</td><td>electrically safe</td></tr>
</table>

Biocompatibility: Results of the biocompatibility testing (**Table 4-4**) indicate that the Kronos Electrocautery Device (Subject Device) is biocompatible and is substantially equivalent for its intended use.

Table 4-4: Biocompatibility Test Summary

Test	Results	Conclusion
Sensitization	There was no irritation noted at any test site 24 or 48 hours after the challenge patch removal for physiological sale (polar extract) or sesame oil (non-polar extract).	Non-sensitizer

Irritation or Intracutaneous	The primary irritation index (PII) of the test article was 1.0 or less.	Non-irritant
Acute Systemic Toxicity	No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 3-day observation period.	Non-cytotoxic
Systemic Toxicity -ISO Materials Mediated Rabbit Pyrogen	During the 3-hour observation period, none of the rabbits administered with the test article extract had a temperature rise ≥0.5ºC at the required observation time points. This response did not exceed the USP limit and meets the requirements for this test. Therefore, these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic

Shelf life: The accelerated shelf life testing for Kronos Electrocautery Device has been conducted (T=2 year accelerated aging) with test results confirmed that all acceptance criteria were met. No new questions of safety or effectiveness are raised. Based on the results, we can conclude that Kronos Electrocautery Device will perform as intended to the Design Specification. Kronos Electrocautery Device will be labeled for 2-year shelf life.

Packaging: The packaging validation, T=2 year accelerated aging was performed on the Kronos Electrocautery Device. The results from packaging testing conducted on Kronos Electrocautery Device showed that the acceptance criteria were met. Therefore, we can conclude the Kronos Electrocautery Device packaging will provide the adequate and effective protection and sterile barrier requirements.

Sterilization: Kronos Electrocautery Device is sterilized using 100% Ethylene Oxide (EtO) gas in the same manner as FDA cleared predicate device, Bovie Cautery Device (K121441). Kronos Electrocautery Device is supplied sterile, for single use and single patient only. The sterilization validation was performed and is documented. The sterilization validation results showed that the sterilization dose and routine sterilization process was validated to achieve an SAL of 10^{-6} for the Kronos Electrocautery Device.

Test Description	**Test Summary**	**Results**
Original Sterilization validation and Adoption	100% EO is used to sterilize the device to achieve a minimum SAL of 10^{-6}. The validation was conducted in accordance with ISO 11135. The original validation of the EO sterilization cycle of a predicate device was performed using one (1) fractional exposure cycle, three (3) half exposure cycles and one (1) full exposure cycle, an overkill approach described in ISO 11135. The subject device was adopted to the original validated sterilization cycle by performing one (1) full cycle.	The validation study demonstrated that the sterilization process and equipment are capable of reliably and consistently sterilizing the devices to a minimum SAL of 10^{-6}. The BI results confirm the acceptable lethality of the sterilization cycle to achieve the required SAL of 10^{-6}. Fractional cycles, half cycles, and full cycles met the acceptance criteria. The subject device was successfully adopted to the original sterilization validation.
EO and ECH Residuals	EO and ECH residuals were measured per ISO 10993-7.	The residual traces of EO and ECH for the subject device are below the limits specified in ISO 10993-7.
EO and ECH Tolerable Contact Limit (TCL)	EO and ECH TCL were measured per ISO 10993-7.	The TCL of EO and ECH for the subject device are below

		the limits specified in ISO 10993-7.
Bacterial Endotoxin Levels	LAL testing was conducted in accordance with FDA guidance document (June 2012), USP<85>, and European Pharmacopeia BET 2.6.14	The test results demonstrated that the bacterial endotoxins were not present above the endotoxin limit specified in FDA guidance document (June 2012), USP<85>, and European Pharmacopeia BET 2.6.14

CONCLUSIONS

We conclude from the indications for use, technological characteristics, and performance testing data and evidence that the subject device, the Kronos Electrocautery Device, is substantially equivalent to and as safe and effective as the predicate device, Bovie Cautery Device.