October 26, 2026

Single Pass, Inc.
Ryan Breckenridge
Head of Regulatory
105 N. Pt.E Dr.
Lake Forest, California 92630

Re: K262720
Trade/Device Name: SP Electrocautery Device (SP18 Max);SP Electrocautery Device (SP20 Max)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 31, 2026
Received: July 31, 2026

Dear Ryan Breckenridge:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.10.26 09:25:53 -04'00'

Colin K. 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262720

Please provide the device trade name(s).

SP Electrocautery Device (SP18 Max);
SP Electrocautery Device (SP20 Max)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

1. Submitter Information (21 CFR 807.92(a)(1))

Applicant:	Single Pass, Inc.
Address:	105 N. Pointe Dr. Lake Forest, CA 92630
Contact:	Ryan Breckenridge, Head of Regulatory
Telephone:	760-917-1294
Email:	regulatory@singlepass.co
Date Prepared:	September 29, 2026

2. Device Name (21 CFR 807.92(a)(2))

Device Trade Name:	SP Electrocautery Device (SP20)
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories Regulation
Number:	878.4400
Device Product Code:	GEI

3. Legally Marketed Predicate and Reference Devices (21 CFR 807.92(a)(3))

Primary Predicate Device:
510(k) Number: K260287
Trade Name: SP Electrocautery Device (SP20)
Manufacturer: Single Pass, Inc.
Product Code: GEI

Secondary Predicate Device:
510(k) Number: K232805
Trade Name: Kronos Electrocautery Device (SP18)
Manufacturer: Single Pass, Inc.
Product Code: GEI

Reference Device:
510(k) Number: K121441
Trade Name: Bovie Cautery Device
Manufacturer: Bovie Medical Corporation
Product Code: HQP

The reference device is used to provide comparative information regarding thermal tissue effects associated with electrocautery and is not relied upon to establish the same intended use as the subject device.

4. Device Description Summary (21 CFR 807.92(a)(4))

The SP Electrocautery Device is a single-use, disposable, battery-powered electrocautery instrument used to achieve hemostasis through coagulation of soft tissue in liver, kidney, and lung. The device consists of an ergonomic handpiece containing two AA alkaline batteries and control electronics connected to a stainless-steel probe shaft with a heated distal segment. When activated, electrical current heats a resistive element near the distal tip, and a thermistor provides feedback to a closed-loop controller to maintain the selected operating temperature. The Single Pass device family includes multiple probe configurations that share the same fundamental operating principle, handle, electronics, power source, temperature-control algorithm, and patient-contact materials.

The subject SP18 MAX and SP20 MAX devices expand the allowable operating temperature range of the cleared SP18 and SP20 configurations from approximately 75–100°C to 75–145°C. The fundamental operating principle, energy source, temperature-control mechanism, intended use, indications for use, patient-contact materials, sterilization method, packaging configuration, labeled shelf life, and intended users remain unchanged.

The basic device description is carried forward from K260287, which describes the battery-powered resistively heated probe and thermistor-based closed-loop temperature control.

5. Intended Use / Indications for Use (21 CFR 807.92(a)(5))

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

The indications for use of the subject device are the same as the primary and secondary predicate devices.

That is the exact indication stated in the previous K260287 Summary.

6. Technological Comparison (21 CFR 807.92(a)(6))

The subject SP18 MAX and SP20 MAX devices have the same intended use and use the same fundamental scientific technology as the primary and secondary predicate devices. The principal technological difference addressed by this submission is expansion of the allowable operating temperature range from approximately 75–100°C to 75–145°C.

The Bovie Cautery Device (K121441) is included as a reference device to provide comparative information regarding thermal tissue effects associated with legally marketed electrocautery technology.

Characteristic	Subject Device – SP18 MAX / SP20 MAX	Primary Predicate – SP20 (K260287)	Secondary Predicate – SP18 (K232805)	Reference Device – Bovie Cautery Device (K121441)
Manufacturer	Single Pass, Inc.	Single Pass, Inc.	Single Pass, Inc.	Bovie Medical Corporation
Product Code	GEI	GEI	GEI	HQP
Intended Use / Indications for Use	Hemostasis through coagulation for liver, kidney, and lung soft tissue	Same as subject device	Same as subject device	stopping small bleeders in hemostasis and other similar uses
Fundamental Technology	Thermal electrocautery	Thermal electrocautery	Thermal electrocautery	Thermal cautery
Energy Source	Two AA alkaline batteries	Two AA alkaline batteries	Two AA alkaline batteries	One or two 1.5-volt alkaline batteries
Heating Method	Resistive heating element near distal probe tip	Same as subject device	Same as subject device	Heated cautery tip
Temperature Control	Thermistor-based closed-loop control	Same as subject device	Same as subject device	Not specified
Allowable Temperature Range	75–145°C	75–100°C	75–100°C	Not specified
Probe / Tip Configuration	18 GA and 20 GA probe configurations	20 GA probe	18 GA probe	Interchangeable cautery tip configurations
Sterility	Sterile, EtO	Same as subject device	Same as subject device	Sterile, EtO
Single Use	Yes	Yes	Yes	Yes

7. Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))

Design verification and validation testing was conducted through established design-control and risk-management processes to evaluate the impact of the expanded allowable operating temperature range.

Non-clinical Testing – Temperature Characterization

Additional temperature characterization testing was conducted to support the expanded operating temperature range. The testing demonstrated the ability of the SP18 MAX and SP20 MAX devices to achieve the expanded temperature range design outputs. The temperature profile was demonstrated to be stable and accurate in a manner consistent with the predicate devices.

Non-clinical Testing – Thermal Safety

Thermal safety testing was conducted to evaluate tissue response associated with the expanded operating temperature range. Testing demonstrated the ability of the SP18 MAX and SP20 MAX devices to achieve the specified cauterization design outputs. Histopathological evaluation characterized the resulting tissue response as mild and localized, without major disruption of adjacent tissue. Increased cross-sectional thermal injury dimensions were observed relative to the cleared configurations in certain tissue/device comparisons and were further evaluated through comparative thermal spread testing using a legally marketed reference device.

Non-clinical Testing – Histopathological Evaluation

Ex vivo histopathological testing was conducted in liver, kidney, and lung tissues to characterize the thermal tissue effects associated with the expanded operating temperature range. The higher-temperature SP18 MAX and SP20 MAX configurations demonstrated increased cross-sectional thermal injury dimensions relative to the cleared SP18 and SP20 configurations in certain tissue/device comparisons. Histopathological evaluation characterized the resulting tissue response as mild and localized, without major disruption of adjacent tissue. The results demonstrated that the increased operating temperature increases the magnitude of the intended thermal tissue effect without introducing a new type or mechanism of tissue injury.

Non-clinical Testing – Comparative Thermal Spread

Additional comparative ex vivo testing was conducted using the Bovie Cautery Device (K121441) as a reference device to contextualize the thermal spread associated with the expanded allowable operating temperature range. The SP18 MAX and SP20 MAX devices and Bovie electrocautery configurations were evaluated under matched test conditions using consistent tissue preparation, insertion depth, activation duration, withdrawal technique, and measurement methodology. Under the matched test conditions, the Bovie configurations produced lateral thermal zones equal to or greater than those produced by the SP18 MAX and SP20 MAX devices based on cross-sectional length and width measurements across the tissues evaluated. These results demonstrate that the lateral thermal effects produced by the subject devices do not exceed those produced by the legally marketed Bovie reference device under the evaluated conditions.

Risk Assessment

Risk management activities were performed to assess the impact of the increased allowable operating temperature. Thermal injury, including excessive heat and unintentional internal and/or external burns, is an existing identified hazard associated with the device. The increased operating temperature increases the magnitude of an existing intended thermal tissue effect but does not introduce a new type of hazard or mechanism of tissue injury. Existing controls addressing device placement, activation, treatment depth, duration of energy delivery, image-guided use, and warnings and precautions were reassessed and determined to remain appropriate for the subject device.

Clinical Testing

No clinical testing was conducted or required for this modification.

8. Substantial Equivalence Conclusion (21 CFR 807.92(b))

The subject SP18 MAX and SP20 MAX devices have the same intended use and use the same fundamental scientific technology as the legally marketed primary and secondary predicate devices.

The primary technological difference is expansion of the allowable operating temperature range from approximately 75–100°C to 75–145°C. Non-clinical performance testing, including device performance testing, histopathological evaluation, comparative thermal-spread testing, and risk assessment, was conducted to evaluate the impact of this difference.

Histopathological testing demonstrated that the tissue effects associated with the expanded temperature range remained mild and localized. Direct comparative testing further demonstrated that the lateral thermal zones produced by the SP18 MAX and SP20 MAX devices did not exceed those produced by the legally marketed Bovie reference device under matched test conditions.

Based on the same intended use, the same fundamental scientific technology, and the non-clinical performance data summarized above, the differences in technological characteristics do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject SP18 MAX and SP20 MAX devices are as safe and effective as the legally marketed predicate devices.

Therefore, the SP Electrocautery Device (SP18 MAX and SP20 MAX) is substantially equivalent to the legally marketed predicate devices.