February 24, 2026

Single Pass, Inc.
% Greg Geissinger
Principal Consultant
Geissinger Regulatory Consulting, Inc.
6 Basilica Place
Ladera Ranch, California 92694

Re: K260287
Trade/Device Name: SP Electrocautery Device (SP20)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 26, 2026
Received: January 29, 2026

Dear Greg Geissinger:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.02.24 14:06:28 -05'00'

For
Colin Kejing Chen, 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

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.	K260287

Please provide the device trade name(s).

SP Electrocautery Device (SP20)

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: Greg Geissinger, Head of Regulatory

Telephone: 858-349-3389

Email: ggeissinger@singlepass.co

Date Prepared: February 19, 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 Device (21 CFR 807.92(a)(3))

Predicate Number: K232805

Predicate Trade Name: Kronos Electrocautery Device

Predicate Product Code: GEI

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 following percutaneous biopsy. 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 a target operating temperature range of approximately 75-100 °C while the clinician advances or withdraws the probe within the biopsy tract.

The Single Pass device family includes multiple probe configurations that share the same handle, electronics, power source, temperature control algorithm, and patient-contact materials. This Special 510(k) introduces a new 20-gauge (GA) shaft configuration (SP20) designed for use through smaller-diameter biopsy tracts. SP20 uses the same internal heater and thermistor design and operates over the same controlled temperature range as the existing configurations. The only physical differences are a reduced shaft outer diameter (20 GA) and a minor distal tip redesign in which the shaft is sealed at the distal end without a separate end cap. Sterilization method (EtO), packaging configuration, labeled shelf life, indications for use, and intended users remain unchanged.

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 are the same as the predicate device.

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

The SP20 device uses the same fundamental scientific technology (battery-powered thermally heated stainless-steel probe with thermistor-based temperature control operating at 75-100 °C) and differs from the predicate only by a reduction in shaft diameter (18 GA to 20 GA) and a minor distal tip redesign (sealed shaft tip without a separate end cap).

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

Design verification and validation testing was identified through established design controls and risk management to evaluate the impact of the SP20 modification. Testing was conducted using well-established methods, including internal protocols used for the legally marketed device family.

Non-clinical testing – Usability (Simulated Use):
A confirmatory simulated-use usability evaluation was conducted to verify that intended clinician users can safely and effectively perform critical tasks for the SP20 configuration in a representative use scenario consistent with the current Instructions for Use.

Non-clinical testing – Thermal characterization (Temperature vs. Time):
Bench thermal characterization testing was performed to evaluate the SP20 temperature-versus-time profile across ramp-up, activation hold period, and ramp-down using an established internal engineering evaluation method with calibrated equipment.

Other non-clinical and clinical testing:
No clinical testing was conducted or required for this modification.

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

Based on the same intended use, the same fundamental scientific technology, and the non-clinical performance data summarized above demonstrating that SP20 meets predetermined acceptance criteria and does not introduce new questions of safety or effectiveness, the SP Electrocautery Device (SP20) 20 GA configuration is substantially equivalent to the legally marketed predicate device.