September 22, 2025

Surgical Principals, Inc.
Timothy Wynne
President and CEO
1625 South Tacoma Way
Pierce, Washington 98409

Re: K251743
Trade/Device Name: SPI LaproSac™ Laparoscopic Single-Use Rip-Stop Nylon Specimen Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 27, 2025
Received: August 27, 2025

Dear Timothy Wynne:

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.

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: 2025.09.22 16:33:44 -04'00'

Colin Kejing Chen
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251743

Device Name

SPI LaproSac™ Laparoscopic Single-Use Rip-Stop Nylon Specimen Retrieval System

Indications for Use *(Describe)*

The LaproSac™ Specimen Retrieval Bags is indicated for use in surgical procedures to capture organs or tissue to be removed from the body cavity during Laparoscopic Surgery.

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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Surgical Principals, Inc.

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510(k) K251743
510(k) SUMMARY

1. SUBMITTER'S CONTACT INFORMATION

Company: Surgical Principals Inc.
Address: 1625 South Tacoma Way, Tacoma, WA 98409
Contact Person: Timothy Wynne
Phone: 888-801-9251
Date Prepared: September 16, 2025

2. DEVICE NAME

Trade Name – SPI LaproSac™ Laparoscopic Single-Use Rip-Stop Nylon Specimen Retrieval Systems
Common Name – Retrieval Bag, Specimen Retrieval Bag
Regulation Number – 21 CFR 876.1500
Classification Name – Laparoscope, General & Plastic Surgery
Product Code – GCJ
Device Classification – Class II
Classification Panel – General and Plastic Surgery

3. PREDICATE DEVICE

The SPI LaproSac™ Laparoscopic Single-Use Rip-Stop Nylon Specimen Retrieval Systems claim Substantial Equivalence to the Espiner Tissue Retrieval System (Sac or E-Sac) under 510(k) K111845.

4. DEVICE DESCRIPTION

The SPI LaproSac™ Laparoscopic Single-Use Rip-Stop Nylon Specimen Retrieval Systems are sterile single patient use devices, which comprise of a flexible nylon bag with and without a deployment mechanism. The bag consists of a large, easily accessible opening and a closure suture that facilitates closure of the specimen bag after the specimen(s) have been collected. The deployment mechanism consists for an introducer and actuation rod with biasing arms, which allows for insertion through an appropriately sized port and automatic opening of the bag upon deployment.

These devices are not made with natural rubber latex or synthetic derivatives of natural rubber latex.

5. INDICATIONS FOR USE

The LaproSac™ Specimen Retrieval Bags is indicated for use in surgical procedures to capture organs or tissue to be removed from the body cavity during Laparoscopic Surgery.

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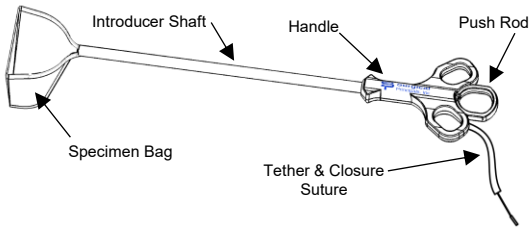
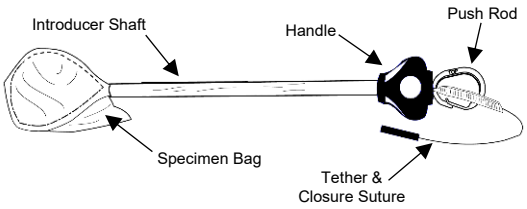
6. SUBSTANTIAL EQUIVALENCE TABLE

Category	Subject Device	Predicate Device
Device	SPI LaproSac™ Laparoscopic Single-Use Rip-Stop Nylon Specimen Retrieval Systems (510(k) K251743)	The Espiner Tissue Retrieval System (K111845)
Classification	Endoscope and Accessories (GCJ)	Same
Intended Use	The LaproSac™ Specimen Retrieval Bags is indicated for use in surgical procedures to capture organs or tissue to be removed from the body cavity during Laparoscopic Surgery.	The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use device that can be used alone of with a dedicated introducer system for encapture and removal of an organ, tissue or fluid from the bag cavity during laparoscopic surgery.
Product Picture		
Design	The LaproSac™ Specimen Retrieval Bags are sterile single patient use devices, which comprise of a flexible nylon bag with and without a deployment mechanism. The bag consists of a large, easily accessible opening and a closure suture that facilitates closure of the specimen bag after the specimen(s) have been collected. The deployment mechanism consists for an introducer and actuation rod with biasing arms, which allows for insertion through an appropriately sized port and automatic opening of the bag upon deployment. These devices are not made with natural rubber latex or synthetic derivatives of natural rubber latex.	The sac includes introduction tab(s) or tether and a drawstring (closure suture). The introduction tab(s) are used as a contact points for the instrument (tether for attachment to the dedicated introducer) for introduction through an appropriately sized cannula. The drawstring facilitates a secure closure of the sac. The dedicated introducer comprises an introducer tube with handle, and push rod. The introducer allows for the bag to be inserted through an appropriately sized port. The push rod assembly comprises a loop on one end and biasing arms on the other, which allow the bag mouth to open upon deployment.
Bag Volume	50 to 6000 mL	Unknown
Introducer / Trocar Diameter	5 to 15mm	Same
Biocompatibility	Conforms to ISO 10993 series of FDA recognized consensus standards and associated FDA Guidance documents on application.	Unknown
Sterilization	Sterilized using Ethylene Oxide for single patient use in accordance with ISO 11135 to an SAL of 10^{-6}.	Sterilized using Ethylene Oxide
Prescription Use	Yes	Yes
Intended Environment	Professional Healthcare Facility (Surgical Room or Operating theatre)	Same

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7. NONCLINICAL TESTS

Nonclinical testing has been conducted to verify that these devices met all design specifications and are substantially equivalent to the predicate device. Testing included the following:

- Biocompatibility Testing performed in accordance with the following:
  - ISO 10993-1: 2018 – Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (Recognition No. 2-258)
  - ISO 10993-5:2009 – Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Recognition No. 2-245)
  - ISO 10993-7:2008 – Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (Recognition No. 14-408)
  - ISO 10993-10:2021 – Biological evaluation of medical devices - Part 10: Tests for skin sensitization (Recognition No. 2-296)
  - ISO 10993-11:2017 – Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (Recognition No. 2-255)
  - ISO 10993-23:2021 – Biological evaluation of medical devices - Part 10: Tests for irritation (Recognition No. 2-291)
- Aging Study per ASTM F1980-21 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (Recognition No. 14-575)
- Ethylene Oxide Sterilization Validation per ISO 11135:2014 – Sterilization of health-care products - Ethylene Oxide (Recognition No. 14-529)

In addition, these devices have been compared to the predicate device through various performance studies designed to test the general device operation, function and integrity. Testing included the following:

- Dimensions: Dimensional measurements of the bag length, width/opening and volume.
- Deployment Operation: Measurement of the bag retraction, deployment, and introduction forces.
- Bag Operation: Measurement of the bag closure force, resulting reduction in the bag opening and force required to reopen the bag.
- Device Integrity (Destruction): Measurement of the tensile strength of the tether, buttonhole, and introduction tabs. Measurement of the bag seam strength per ASTM F88/F88M and puncture resistance per MIL-STD-3010C Method 2065.

8. CLINICAL TESTS

There were no clinical trials performed on these devices.

9. CONCLUSIONS

The subject device has equivalent indications for use as the predicate device. There are no new technologies being added to this device from the predicate, in terms of finished device functions. The device has the same intended use and application as the predicate device.