Sejong Medical Co., Ltd.
Jinho Kim
Manager
11, Sinchon 2-ro Paju-si
Gyeonggi-do
Paju-si, Gyeonggi-do 10880
Republic Of Korea

May 19, 2026

Re: K252985
Trade/Device Name: Laport
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: July 4, 2025
Received: September 18, 2025

Dear Jinho Kim:

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 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: 2026.05.19 22:07:24 -04'00'

Colin K. 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.	K252985

Please provide the device trade name(s).

Laport

Please provide your Indications for Use below.

The Laport Trocars have applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.

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

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

SEJONG MEDICAL CO., LTD.

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510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: Not yet assigned

01. Date of Submission: September 19, 2025

02. Applicant / Submitter

SEJONG MEDICAL CO., LTD.
11, Sinchon 2-ro, Paju-si, Gyeonggi-do, Republic of Korea

03. Submission Correspondent

Jinho Kim
SEJONG MEDICAL CO., LTD.
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04. Subject Device Identification

Trade/Device name: Laport
Classification name: Endoscope and Accessories
Common name: Trocar
Device Class: Class II
Regulation Number: 21 CFR 876.1500
Product Code: GCJ
Review Panel: General & Plastic Surgery

Indication for use:

Laport Trocars have applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.

05. Predicate Device Identification

510(k) Number: K171741
Device Name: Laport®
Manufacturer: SEJONG MEDICAL Co., Ltd.

SEJONG MEDICAL CO., LTD.

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06. Device Description

The Laport Trocars are for use during endoscopic minimally invasive procedures or to gain access potential spaces for endoscopic instruments. The Laport Trocars are consisting of a sleeve and needle in sizes ranging from 5 to 12 mm in diameter. There are three different needles: Blade, Optical and Bladeless Type. The Blade Type has a sharp flat-bladed tip and shield. The shield on the Blade Type needle is designed to cover the flat-bladed tip to protect internal structures from puncture once the abdominal or thoracic cavity has been entered. The Optical Type has a transparent tip for use with an endoscope to provide visualization for insertions. The Bladeless Type has a plastic tip which reduces hazards during puncture of abdominal cavity.
The Hassan blunt trocar is equipped with a cone featuring an integrated locking mechanism, allowing the insertion depth of the cannula to be precisely adjusted according to the surgical requirement. In addition, the cannula assembly incorporates dedicated suture stay posts, enabling secure anchoring of the device to the patient's skin tissue and minimizing the risk of displacement during the procedure.

07. Summary of Technological Characteristics Comparison

The Laport has the same intended uses, principle of operation and the same technical characteristics and functionality as predicate devices.

Product Name	Subject Device Laport K_____	Predicate Device Laport K171741	Equivalence Discussion
Manufacturer	SEJONG MEDICAL Co., Ltd.	SEJONG MEDICAL Co., Ltd.	Same
Product code / Regulation	GEI / 21 CFR 878.4400	GEI / 21 CFR 878.4400	Same
Classification	Class II	Class II	Same
Intended use	Laport Trocars have applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments	Laport® Trocars have applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments	Same
Operation Principles	Sterile Trocars for Endoscopic surgery, Laport , is a sterile single use device and is intended to establish a path of entry for endoscopic instruments for use during general, abdominal, gynaecological and thoracic minimally invasive procedures or to gain access through tissue planes and/or potential spaces for endoscopic instruments.	Sterile Trocars for Endoscopic surgery, Laport® , is a sterile single use device and is intended to establish a path of entry for endoscopic instruments for use during general, abdominal, gynaecological and thoracic minimally invasive procedures or to gain access through tissue planes and/or potential spaces for endoscopic instruments.	Same
Main component	Sleeve, Needle	Sleeve, Needle	Same
Needle Type	Blade Bladeless Optical	Safety Bladeless, Optical	Different
Material	Polycarbonate, ABS, Stainless Steel, Silicone	Polycarbonate, ABS, Stainless Steel, Silicone	Different
Single-Use/ Reuse	Single-use	Single-use	Same
Sterilization	Sterile (EtO sterilization)	Sterile (EtO sterilization)	Same
Shelf life	Five years from date of sterilization	Five years from date of sterilization	Same

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The subject device described in this 510(k) has the same intended use and technological characteristics as the predicate device (Laport, K171741). The primary modifications are the addition of the Hassan Universal and the Universal Long model, changes to patient-contacting and non-patient-contacting materials of the predicate device, and the renaming of the needle type from "safety type" to "blade type." To verify the safety and effectiveness of these modifications, a representative model was selected for biological safety and stability testing. Based on the submitted test results, these modifications do not affect the safety or effectiveness of the device, and the subject device is substantially equivalent to the predicate device.

08. Non-clinical Testing Data

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the new device. The device passed all of the tests based on pre-determined pass/fail criteria. We have referenced the following standards when developing and validating the subject device.

- Sterilization Validation Test in accordance with ISO11737-1
- Shelf Life Validation Test in accordance with ASTM F 1980
- Biocompatibility Tests in accordance with ISO 10993

Cytotoxicity	ISO 10993-5
Ethylene Oxide Sterilization Residuals	ISO 10993-7
Skin Sensitization	ISO 10993-10
Irritation	ISO 10993-23
Acute systemic toxicity	ISO 10993-11,
Pyrogen	ISO 10993-11, USO-NF 2023<151> Pyrogen test

- Performance Tests:
  - Air tightness test
  - Blade safety operation system test
  - Penetration force test
  - Extraction force test
  - Insufflation performance test

09. Clinical Testing

Clinical testing is not a requirement and has not been performed.

10. Substantial Equivalence Conclusion

The new device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not introduce a fundamentally new scientific technology, and the nonclinical tests demonstrate that the subject device is substantially equivalent to the predicate device.