DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 29, 2017

Sejong Medical Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc
690 Roosevelt
Irvine, California 92620

Re: K171741
Trade/Device Name: Laport
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 5, 2017
Received: June 12, 2017

Dear Ms. Chung:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171741

Device Name

Laport ®

Indications for Use *(Describe)*

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(K171741)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 08/24/2017

1. Submitter/Applicant

Sejong Medical Co., Ltd.
11, Sinchon 2-ro
Paju-si, Gyeonggi-do
Republic of Korea 10880

Tel: +82-31-945-8191
Fax: +82-31-945-8190

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
690 Roosevelt, Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Laport ®
- Common Name: Sterile Trocars for Endoscopic surgery
- Classification: Class II
- Classification regulation: 21 CFR 876.1500
- Product Code: GCJ

4. Predicate Devices:

Primary Predicate Device:
ENDOPATH® III Trocars (K032676) by Ethicon Edo-Surgery, Inc.
Reference Predicate Deice:
LAPORT (K092584) by MGB EndoskopischeGerate GmbH Berlin

5. 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: Safety, Optical and Bladeless Type. The Safety Type has a sharp flat-bladed tip and shield. The shield on the Safety 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.

6. Indication for use:

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

7. Performance Data

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

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

Cytotoxicity	ISO 10993-5
Ethylene Oxide Sterilization Residuals	ISO 10993-7
Skin Sensitization	ISO 10993-10
Systemic Toxicity	ISO 10993-11
Irritation	ISO 10993-10

- Performance Tests: Appearance, Measurement, Leakage, and Extraction, and Non-Clinical(Animal) test

Test	Test Method
Appearance	Visual Inspection
Measurement	Inspecting dimensions using vernier calipers
Leakage	When the sample was put air in trocar sleeve with air pressure after close the valve, it should not be leaked.
Extraction Test	Appearance, pH, KMnO4, Evaporating

	residue, Heavy Metal, UV-vis Spectrum
Non-Clinical(Animal) test using micropigs	Trocar Insertion & Extraction Test: The operator (expert veterinarian) scored the experience when the trocar was inserted into the abdominal cavity of animals and extracted according to pre-set scoring index. Insertion, Fixation, and Extraction were evaluated.
	Intraperitoneal Pressure Test: The time for intraperitoneal pressure to reach a certain mmHg was recorded. And the bubble test was performed to check the leakage of gas. Time to insufflation was evaluated.
	Convenience of performing laparoscope: The operator inserted the laparoscope thought the trocar needle of optical test devices and scored the convenience of performing laparoscope according to the scoring index demonstrated below. Visualization was also evaluated.

All the test results demonstrated that the subject device is substantially equivalent to the predicate devices.

8. Basis for Substantial Equivalence

The subject device, Laport® incorporates the same intended use with the predicate devices. The subject device is composed of similar materials with the predicate devices. All the devices are similar in physical & mechanical properties.
The differences between the subject device and the predicate device are universal seal and lip valve part. The subject device, Laport® has a universal seal that facilitate using a wide range of instruments from 5mm to 12mm.
We have performed the various performance tests, and the test results support that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

Upon reviewing the information including testing data provided in this submission and comparing intended use, principle of operation and overall technological characteristics, we conclude that the Laport® is substantially equivalent to the predicate devices.