DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2017

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

Re: K171726
Trade/Device Name: LapBag
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 12, 2017
Received: September 19, 2017

Dear Priscilla 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)*

K171726

Device Name

LapBag®

Indications for Use *(Describe)*

LapBag® is intended for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

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

(K171726)

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

Date: 09/12/2017

1. Submitter/Applicant

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: LapBag®
- Common Name: Tissue Bags
- Classification: Class II
- Classification regulation: 21 CFR 876.1500
- Product Code: GCJ

4. Predicate Devices:

Predicate Device:
MGB Disposable Retrieval Bag/LAPBAG (K093194) by MGB Endoskopische Gerate GmbH Berilin

5. Description:

Sterile Specimen Retrieval Pouch, LapBag®, is a single use specimen container. It is

designed for use in retrieving specimens during laparoscopic surgery. The LapBag® single use specimen retrieval pouch is supplied sterile in a dispensing tube for ease of insertion through a standard 5, 10, 11,12mm trocar cannula (sleeve). There are 4 types: metal type, non-metal type, metal locking type, and non-metal locking type.

6. Indication for use:

LapBag® is intended for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

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, Extraction Test, Puncture Resistance and Tensile Strength tests, Bag Leak Test, and Ring Pull Test

8. Basis for Substantial Equivalence

The subject device, LapBag® incorporates the same intended use with the predicate device. The devices are similar in physical & mechanical properties and dimensions.

The major difference between the subject device and the predicate device is the sizes of pouch. LapBag® has a wider range of size than the predicate devices. We have performed the comparison test for Puncture Resistance, Tensile Strength, Bag Leak Test, and Ring Pull Test, 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 LapBag® is substantially equivalent to the predicate devices.