April 3, 2020

Sejong Medical Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K200638
Trade/Device Name: LAP-iX Suction Irrigation
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: Class II
Product Code: HET
Dated: February 25, 2020
Received: March 10, 2020

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200638

Device Name
LAP-iX Suction Irrigation

Indications for Use *(Describe)*
The LAP-iX Suction Irrigation provides suction or irrigation to a surgical site during laparoscopic and endoscopic 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.

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510(k) Summary

(K200638)

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

Date: 04/03/2020

1. Submitter/Applicant

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: LAP-iX Suction Irrigation
- Common Name: Gynecologic laparoscope and accessories
- Classification: Class II
- Classification regulation: 21 CFR 884.1720
- Product Code: HET

4. Predicate Devices:

LAP-iX Suction Irrigation (K173111) by Sejong Medical Co., Ltd.

5. Description:

The LAP-iX Suction Irrigation provides suction or irrigation to a surgical site during laparoscopic and endoscopic procedures. It delivers sterile irrigation fluids to surgical site and evacuates blood and body fluids from the surgical site to aid visualization. It consists of 4.5Ø diameter shaft, suction/irrigation buttons and

suction/irrigation tubes with hand piece. It has two types of hand piece, pistol and trumpet grip. The subject device is compatible with all suction and irrigation pumps in the market which have the connecting tubes or connectors of Ø10mm (Suction) or Ø7mm(Irrigation). All equipment conforming to this specs can be used.
It is provided sterile, for Rx only and single use.

6. Indication for use:

The LAP-iX Suction Irrigation provides suction or irrigation to a surgical site during laparoscopic and endoscopic procedures.

7. Performance Data

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified 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 10993-10

- Performance Tests: Air tightness, Suction and Irrigation Test

8. Basis for Substantial Equivalence

The subject device described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device (LAP-iX Suction Irrigation, K173111).

The differences are that the subject device has longer tubes with the new material, and also the link design for some models has slightly changed as well to fit the extension tubes better.
Based on the test results submitted in this 510K, we conclude that these differences do not raise a question in safety and effectiveness and the subject device is substantially equivalent to the predicate device.

9. 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.