September 29, 2021

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

Re: K200639
Trade/Device Name: LAP-iX
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 22, 2021
Received: July 28, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200639

Device Name
LAP-iX

Indications for Use *(Describe)*
LAP-iX is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site.

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

(K200639)

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

Date: 09/27/2021

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.
1150 Roosevelt STE 200, Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: LAP-iX
- Common Name: Electrosurgical Cutting and coagulation device and accessories
- Classification: Class II
- Classification regulation: 21 CFR 878.4400
- Product Code: GEI

4. Predicate Devices:

LAP-iX (K173112) by Sejong Medical Co., Ltd.

5. Description:

The LAP-iX provides suction or irrigation and conducts high-frequency monopolar electrosurgical energy from compatible electrosurgical generators 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. They are used during endoscopic, and laparoscopic surgical procedures to ablate, remove, resect, and coagulate soft tissue where associated hemostasis is required.

Depending on the shape of the handle, there are two types, PISTOL Type and TRUMPET Type. PISTOL Type has pistol grip handle design. TRUMPET Type has Trumpet grip handle design.

The electrode offers three types: L-HOOK, SPOON and J-HOOK Type. All three electrode types are compatible with the PISTOL Type and the TRUMPET Type. The L-Hook & J-Hook electrode tip has a sharp contact surface that facilitates cutting especially for thin and long tissue. The SPOON electrode tip is mainly used for large area tissue and also for hemostasis procedure as well.

The voltage should not exceed 175Vrms (300Ω standard), and set to minimum power (100W, 300Ω standard). The connector of the subject device is compatible with all suction/irrigation pumps and electrosurgical generator in the market which have the connecting tubes or connectors of Ø10mm (Suction), Ø7mm(Irrigation) and Ø4mm(Electrode).
All equipment conforming to this specs can be used.

6. Indication for use:

LAP-iX is a sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site.

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, Continuity, Dielectric Strength, HF Leakage Current, Tensile Strength, Cut & Coagulation Button Function, Electrode Cover, Suction & Irrigation Test, Thermal Effect Study

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, K173112).

The subject device and the predicate devices are substantially equivalent, having the same indications for use and the technological characteristics. The modifications are changing banana jack to cable, adding Cut/Coag buttons, electrode length change, new electrode shape, tube length/material change, and also the link design change. 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.