November 21, 2017

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

Re: K173112
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: September 27, 2017
Received: September 29, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K173112

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
(K173112)

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

Date: 11/17/2017

1. Submitter/Applicant

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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:

CONMED UNIVERSAL PLUS (K934828) by CONMED CORP

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 open, 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. Each type also offer both Unlock Type and Lock Type. There are 8 models in total. Unlock type model does not have S lock key and it has a stopper. The stopper has no specific function; it is just to show that the model is the Unlock Type. The Unlock type works only when S / I key is pressed. When the button is not pressed, the device stop working. The Lock Type keeps suction function when S key is pressed once. Pressing the S lock key turns off the suction function.

The electrode offers two types: L-HOOK and SPOON Type. The both electrode types are compatible with the PISTOL Type and the TRUMPET Type. The L-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 (banana jack) 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. The following devices are the examples of the compatible devices.

Electrosurgical Unit

Device Name	ForceTriad™ Electrosurgical Generator	MEGA Power
Applicant Name	Covidien	MEGADYNE
510(K) Number	K102913	K050579

Suction/Irrigation Pump

Device Name	Aqua-Purator
Applicant Name	WISAP
510(K) Number	K982518

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

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
Irritation	ISO 10993-10

- Performance Tests: Surface (visual inspection), Nominal size, Leakage, Continuity, Dielectric Strength Test of Electrode cable, HF Leakage current Test of Electrode cable, and Tensile Strength Test of Electrode cable

8. Basis for Substantial Equivalence

The subject device device, LAP-iX, is substantially equivalent to the predicate device, CONMED UNIVERSAL PLUS (K934828). Both the device has the exactly the same Indications for Use statement. The both devices provide suction and irrigation functions, and conducts high-frequency monopolar electrosurgical energy from compatible electrosurgical generators to a surgical site during laparoscopic and endoscopic procedures. They offer both straight and pistol handle types. The raw material for the electrode is the same between the devices which is stainless steel.

The length of the electrode of the subject device is slightly longer than the predicate device, however, 2cm difference does not raise a questions in safety and effectiveness based on the performance test results including the tensile strength test. Based on this, we determined that the subject device is substantially equivalent to the predicate device.

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 LAP-iX is substantially equivalent to the predicate device.