November 28, 2017

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

Re: K173111
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: September 26, 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)*
K173111

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
(K173111)

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

Date: 11/22/2017

1. Submitter/Applicant

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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:

Surgiwand II (K903207) by COVIDIEN

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. The following devices are the example of the compatible device.

Suction/Irrigation Pump

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

Device Name	Cassette Pump
Applicant Name	Stryker
510(K) Number	K042454

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

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, Tensile strength, Ethylene Oxide Sterilization Residuals, Sterility Test

8. Basis for Substantial Equivalence

The subject device device, LAP-iX Suction Irrigation, is substantially equivalent to the predicate device, Surgiwand II (K903207). Both the devices have the same Indications for Use statement except the fact the subject device does not include

cautery procedure. However, this difference does not raise a question since the subject device does not introduce a new intended use. The both devices provide suction and irrigation functions during laparoscopic procedures. The raw material for the tube is the same between the devices which is stainless steel.
The difference is that the subject device offers an additional handle type which is the pistol handle. However, this difference does not raise a question since the handle type is just for the user's preference and does not affect safety and performance.
Another difference is dimension that the tube diameter of the subject device is slightly smaller than the predicate device and its length is slightly longer than the predicate device. However, the difference is very small that it would not raise a question in safety and effectiveness according to the performance test results including the tensile strength test. Based on the information submitted herein, 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 Suction Irrigation is substantially equivalent to the predicate devices.