April 30, 2021

LivsMed Inc.
Dong Wook Lee
QMR (Quality Management Representative)
#304, D-dong, 700, Pangyo-ro, Bundang-gu 13516
Seongnam-si, Gyeonggi-do
Republic of Korea

Re: K203580
Trade/Device Name: ArtiSential Laparoscopic Instruments-Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 5, 2021
Received: March 8, 2021

Dear Dong Wook Lee:

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)*
K203580

Device Name
ArtiSential Laparoscopic Instruments-Electrodes

Indications for Use *(Describe)*
ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are indicated for cutting and coagulation in endoscopic, gynecological, and general abdominal and thoracic and general laparoscopic 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K203580

510(k) Summary

1. General Information

Applicant/Submitter: LivsMed Inc.

Address: #304, D-dong, 700, Pangyo-ro, Bundang-gu, 13516
Seongnam-si, Gyeonggi-do, Republic of Korea
Tel) +82-70-4282-7652
Fax) +82-31-706-3211

Contact Person: Dong Wook Lee / QMR
(Quality Management Representative)

Address: #304, D-dong, 700, Pangyo-ro, Bundang-gu, 13516
Seongnam-si, Gyeonggi-do, Republic of Korea
Tel) +82-70-7709-4993
Fax) +82-31-706-3211
Email) dongwook.livsmed@gmail.com

Preparation Date: 01-27-2021

2. Device Name and Code

Device Trade Name	ArtiSential Laparoscopic Instruments-Electrodes
Common Name	Electrosurgical Instruments
Classification Name	Electrosurgical, cutting & coagulation & accessories
Product Code	GEI
Regulation Number	21 CFR 878.4400
Classification	Class II
Review Panel	General & Plastic Surgery

3. Predicate Device and Reference Device

ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are substantially equivalent to the following devices.

Table 3.1 Predicate device

Applicant	Device Name	510(k) Number
LivsMed Inc.	ArtiSential Laparoscopic Instruments-Electrodes	K200501

Table 3.2 Reference Device

Applicant	Device Name	510(k) Number
DANNIK	DANNIK Disposable Monopolar Laparoscopic Instruments	K201063

4. Device Description

This product is sterile, single-use, invasive instrument that used in laparoscopic surgery. There are two Version, one for Dissector and Scissors. The two models are same except for jaw. This product is a specific component, but not the entire electrosurgical device. The device is not intended to be marketed with multiple components, accessories, and as part of a system.

5. Indications for Use

5.1 Indications for use

ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are indicated for cutting and coagulation in endoscopic, gynecological, and general abdominal and thoracic and general laparoscopic procedures.

6. Technical Characteristics in Comparison to Predicate Device and Reference Device

Table 6.1 Substantial Equivalence Assessment of Proposed device and predicate device and reference device

	Proposed device	**Predicate Device**	**Reference device**	**Substantial Equivalence**
510(K) Number	K203580	K200501	K201063	N/A
Manufacture	LivsMed Inc.	LivsMed Inc.	DANNIK	N/A
Device Name	ArtiSential Laparoscopic Instruments-Electrodes	ArtiSential Laparoscopic Instruments-Electrodes	DANNIK Disposable Monopolar Laparoscopic Instruments	N/A
Clearance Date	N/A	05-11-2020	06-09-2020	N/A
Classification / Regulation	Class 2 / 878.4400	Class 2 / 878.4400	Class 2 / 878.4400	N/A
Product Code	GEI	GEI	GEI	Same
Intended for	Prescription Use	Prescription Use	Prescription Use	Same

Indications for Use	ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series have application in endoscopic, gynecological, and general abdominal and thoracic and general laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery.	ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series have application in endoscopic, gynecological, and general abdominal and thoracic and general laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery.	The DANNIK Disposable Monopolar Laparoscopic Instrument have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.	Same
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency	Same
Electrode type (monopolar or bipolar)	Monopolar	Monopolar	Monopolar	Same
Jaw type	Dissector, Scissors	Hook, Spatula	Dissector, Scissors	Same
Physical dimensions and design (size, length)	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 3mm, 5mm - Shaft Length: 330mm	Same
Sterilization	EO	EO	EO	Same

7. Performance Data

7.1 Biocompatibility

The device has been evaluated for its biological safety according to ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process". Following endpoints have been assessed during the evaluation:

- Cytotoxicity

- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity

7.2 Electrical Safety

The ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series have been tested according to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-18 and IEC 60601-2-2.

The device had passed all performed tests.

7.3 Sterilization

ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are provided sterile, intended to be single-use. This product is EO-Sterilization in accordance with ISO-11135.

7.4 Shelf life

The proposed expiration date is 2 years from the manufacturing date.
Following tests were conducted both zero time point and 2 years accelerated aging point and the device had passed all tests as below.

1) Packaging and sterility test
   - Packaging integrity test
   - Sealing strength test of packaging (per ASTM F 88)
   - Dye penetration test (per ASTM F1929-15)
   - Sterility test (per ISO 11737- 2:2009)

2) Performance test
   - Appearance
   - Dimension
   - Operational test
   - Tensile Strength
   - Feedthrough test

7.5 Performance test

The device had passed all performed tests as below.

- Appearance
- Dimension
- Operational test
- Tensile Strength
- Feedthrough test

7.6 Thermal effect

Thermal effects testing was conducted on liver, kidney, abdominal muscle at three different power settings (10, 40, and 300W).

Based on these performance characteristics, the results demonstrate that the performance requirements were met, the device performs as intended and that the subject device has substantially equivalent performance characteristics to the predicate device.

8. Substantial Equivalence

Indication for use, principles of operation, energy type, electrode type, jaw type, physical dimension, rated voltage, materials (electrode, shaft), articulating feature, tip rotation, sterilization method of the proposed ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are as same as the predicate device. Although there is a minor difference of raw material (insulation) between the ArtiSential Monopolar Series and the predicate device, the difference does not raise new or different questions of safety and efficacy. There is no new technology and no difference that would raise new or different questions of safety or efficacy.

9. Conclusions

In conclusion, the comparison carried out covers all products, models, sizes, and the entire intended purpose of the device under evaluation. The subject device which is the ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are considerably as same as the predicate device in principles of operation, technological characteristics, as well as performance characteristics. The testing was conducted to evaluate the performance of subject device in comparison to the predicate device. Results of validation and verification activities in design control that include testing/certification to designated standards and performance testing of the device has demonstrated substantial equivalence of the subject device to the predicate in terms of safety and effectiveness for requested intended use.