June 17, 2020

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

Re: K200875
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: May 18, 2020
Received: May 21, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
~~N/A~~ K200875

Device Name
ArtiSential Laparoscopic Instruments-Electrodes

Indications for Use *(Describe)*
Indications for use include electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical 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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Special 510(k) Summary

1. General Information

Applicant/Submitter: LivsMed Inc.

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Contact Person: Dong Wook Lee / QMR
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Email) dongwook.livsmed@gmail.com

Preparation Date: 05-15-2020

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 Devices

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

Table 3.1 Predicate device

Applicant	Device Name	510(k) Number
Livsmed Inc.	ArtiSential Bipolar Fenestrated Forceps	K190909

4. Device Description

The ArtiSential Laparoscopic Instruments – Electrodes, Bipolar series are sterile, single-use, invasive instruments that used in laparoscopic surgery. There are three versions, ABF01 series, ABD01 series and ABD02 series. Three versions are same except for jaw shape. 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 / Intended Use

5.1 Intended Use

The ArtiSential Laparoscopic Instruments – Electrodes, Bipolar series are invasive instruments which is used with electrosurgical generator. They are intended to be used during laparoscopic surgical procedures for incision/coagulation (to electrocauterize, grasp and dissect tissue) during surgery.

5.2 Indications for use

Indications for use include electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.

6. Technical Characteristics in Comparison to Predicate Devices

Table 6.1 Predicate Device

	Proposed device	Predicate Device
510(K) Number	In process	K190909
Manufacture	LivsMed, Inc.	LivsMed, Inc.
Device Name	ArtiSential Laparoscopic Instruments-Electrodes	ArtiSential Bipolar Fenestrated Forceps
Clearance Date	N/A	02-13-2020
Classification / Regulation	Class 2 / 878.4400	Class 2 / 878.4400
Product Code	GEI	GEI
Intended for	Prescription Use	Prescription Use
Indications for Use	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.
Principles of operation	This product is a single-use instrument used in electrosurgical units to hold soft tissues or coagulate and make an incision (tissue dissection) during general laparoscopic surgery, which uses the principle of applying high-frequency currents from the electrode to the human body to generate heat by bioimpedance when radio frequency (RF) energy from the electrosurgical unit applies an electric current to the electrode part, and using the generated	This product is a single-use instrument used in electrosurgical units to hold soft tissues or coagulate and make an incision (tissue dissection) during general laparoscopic surgery, which uses the principle of applying high-frequency currents from the electrode to the human body to generate heat by bioimpedance when radio frequency (RF) energy from the electrosurgical unit applies an electric current to the electrode part, and using the generated

	heat to incise cellular tissues and cause coagulation. It is composed of a jaw, Φ8 diameter shaft, grip (including a control ring), and electrosurgical unit connection electrode connector. During a procedure with this product, the jaw opens if the control ring opens, and jaw closes if the control ring closes. In addition, the jaw is also bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the jaw can also turn 360° when rotating the grip.	heat to incise cellular tissues and cause coagulation. It is composed of a jaw, Φ8 diameter shaft, grip (including a control ring), and electrosurgical unit connection electrode connector. During a procedure with this product, the jaw opens if the control ring opens, and jaw closes if the control ring closes. In addition, the jaw is also bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the jaw can also turn 360° when rotating the grip.
Energy Type	Radiofrequency	Radiofrequency
Electrode type (monopolar or bipolar)	Bipolar	Bipolar
Physical dimensions and design (size, length)	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 8mm - Shaft Length: 380mm
Rated voltage	200Vp	200Vp
Materials (electrode)	Stainless steel	Stainless steel
Materials (insulation)	Polyetherimide	Polyetherimide
Materials (Shaft)	Glass fiber	Glass fiber
Articulating feature	Pitch:±80° or more, Yaw:±80° or more and Open-Close	Pitch:±80° or more, Yaw:±80° or more and Open-Close
Tip rotation	360°	360°
Sterilization	EO	EO

7. Performance Data

7.1 Biocompatibility

The characteristics associated with biocompatibility are the same as in the predicate device K190909.

7.2 Electrical Safety

The ArtiSential Laparoscopic Instruments-Electrodes, Bipolar 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 test setup included:

- Active accessory insulation
- Active accessory hf leakage
- Active accessory hf dielectric strength
- Active accessory mains frequency dielectric strength

- Feedthrough test

  The device had passed all performed tests.

7.3 Sterilization

ArtiSential Laparoscopic Instruments-Electrodes, Bipolar Series are provided sterile, intended to be single-use. This part is same with the predicate device K190909.

7.4 Shelf life

The proposed expiration date is 2 years from the manufacturing date. These characteristics are same with the predicate device K190909.

7.5 Performance test

The device had passed all performed tests.

- Appearance
- Dimension
- Operational test
- Tensile strength
- Feedthrough test
- Grasping Force
- Force to jaw failure

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 devices.

8. Substantial Equivalence

ArtiSential Laparoscopic Instruments-Electrodes, Bipolar Series indication for use is same to the predicate device (K190909). The energy type, electrode type, sterilization as well as physical characteristics are the same. Although there are some minor differences with each product, these differences between the ArtiSential Bipolar Series and the predicate device do 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, Bipolar Series are same to 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 devices has demonstrated substantial equivalence of the subject device to the predicate in terms of safety and effectiveness for requested intended use.