April 26, 2023

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

Re: K230499
Trade/Device Name: ArtiSential Laparoscopic Instruments-Electrodes, Bipolar series (four versions, ABF01series, ABD01 series, ABD02 series and ABD04 series)

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 24, 2023
Received: February 24, 2023

Dear Dong 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,

Mark Trumbore, 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

3. Indications for Use Statement

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)*
K230499

Device Name
ArtiSential Laparoscopic Instruments-Electrodes, Bipolar series (four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 series)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. General Information

Applicant/Submitter: LivsMed Inc.

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

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Fax) +82-31-706-3211
Email) dongwook.livsmed@gmail.com

Preparation Date: 02-24-2023

2. Device Name and Code

Device Trade Name	ArtiSential Laparoscopic Instruments-Electrodes, Bipolar Series (four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 series)
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(four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 series) are substantially equivalent to the following devices

Table 3.1 Predicate device 1

Applicant	Device Name	510(k) Number
LivsMed Inc.	ArtiSential Bipolar Fenestrated Forceps	K200875

Table 3.2 Predicate device 2

Applicant	Device Name	510(k) Number
LivsMed Inc.	ArtiSential Bipolar Fenestrated Forceps	K220384

4. Device Description

The ArtiSential Laparoscopic Instruments – Electrodes, Bipolar series(four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 series) are sterile, single-use, invasive instruments that used in laparoscopic surgery. There are four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 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 for use

5.1 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 1**	**Predicate Device 2**
510(K) Number	In process	K200875	K220384
Manufacture	LivsMed, Inc.	LivsMed, Inc.	LivsMed, Inc.
Device Name	ArtiSential Laparoscopic Instruments-Electrodes	ArtiSential Laparoscopic Instruments-Electrodes	ArtiSential Laparoscopic Instruments-Electrodes
Clearance Date	N/A	05-21-2020	02-24-2022
Classification / Regulation	Class 2 / 878.4400	Class 2 / 878.4400	Class 2 / 878.4400
Product Code	GEI	GEI	GEI
Intended for	Prescription Use	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.	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 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.	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.	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.
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency
Electrode type (monopolar or bipolar)	Bipolar	Bipolar	Bipolar
Physical dimensions and design (size, length)	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm
Rated voltage	200Vp	200Vp	200Vp
Materials (electrode)	Stainless steel	Stainless steel	Stainless steel

Materials (insulation)	Polyetherimide	Polyetherimide	Polyetherimide
Materials (Shaft)	Glass fiber	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	Pitch:±80° or more, Yaw:±80° or more and Open-Close
Tip rotation	360°	360°	360°
Sterilization	EO	EO	EO

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
- Intracutaneous reactivity
- Skin Sensitization
- Acute systemic toxicity
- Pyrogenicity

7.2 Electrical Safety

The ArtiSential Laparoscopic Instruments-Electrodes, Bipolar Series(four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 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:

The device had passed all performed tests.

7.3 Sterilization

ArtiSential Laparoscopic Instruments-Electrodes, Bipolar Series(four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 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 3 years from the manufacturing date. The real-time testing will be performed to confirm the shelf-life for 3 years

7.5 Performance test

The device had passed all performed tests.

Test clause and specification	Test requirement	Results- Remarks
1. Appearance : Implement the visual inspection for surface of the device	There should be no defects in the appearance of the product and there should be no problem in use.	No crack, stain or no substances on the surface of the product
2. Dimension : Measure by ruler and vernier calipers	It shall be within ± 5% of the indicated value of the dimensional term.	Pass Refer to [Test result] on 9-50 page at attachment 12
3. Operational test : Manipulating the grip and control ring, and measure the angle at bending and rotation by goniometer.	The jaw must be smoothly opened and closed and free from jamming, the jaw and hub can be bent up, down, left, and right a range of above ±80° and are capable of 360° rotation.	The jaw and hub are bent up, down, left and right within above 80° and can rotate 360°.
4. Tensile strength : Hold the jaw and shaft connections respectively and apply a force of 20 N using Push pull gauge.	The jaw and shaft connections shall not be damaged from pulling of 20 N.	No damage to the connection when applying a force of 20N
5. Feedthrough test : Electrical conduction between the electrode tip and the connector is tested using a DMM (digital multi meter).	Electricity should be transmitted between the electrode tip and the connector.	The resistance value between the electrode tip and the connector is less than 1Ω

7.6 Thermal effect

Thermal effects on tissue were also tested. A histological analysis was performed on thermal effect to porcine tissues(liver, kidney and abdominal muscle) through an electrosurgical device.

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(four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 series) indication for use is same to the predicate device 1 (K200875) and predicate device 2 (K220384). 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(four versions, ABF01 series, ABD01 series, ABD02 series and ABD04 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.