May 11, 2020

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

Re: K200501
Trade/Device Name: ArtiSential Laparoscopic Instrument-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 16, 2020
Received: March 17, 2020

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,

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)*
K200501

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.

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510(k) Summary

1. General Information

Applicant/Submitter: LivsMed Inc.

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Contact Person: Dong Wook Lee / QMR
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Preparation Date: 02-18-2020

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, Monopolar Series are substantially equivalent to the following devices

Table 3.1 Predicate device

Applicant	Device Name	510(k) Number
Covidien LP	SILS™ L-Hook	K091869

510(k) Summary

Table 3.2 Reference device

Applicant	Device Name	510(k) Number
Livsmed Inc.	ArtiSential Bipolar Fenestrated Forceps	K190909
Purple Surgical International Limited	Laparoscopic Electrodes & Monopolar cables	K142868

4. Device Description

This product is sterile, single-use, invasive instrument that used in laparoscopic surgery. There are two Version, one for Hook and Spatula. 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

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 Devices

Table 6.1 Predicate Device

	Proposed device	**Predicate device**	**Equivalence**
510(K) Number	In process	K091869	N/A
Manufacture	LivsMed, Inc.	Covidien LP	N/A
Device Name	ArtiSential Laparoscopic Instruments-Electrodes	SILS^{TM}L-Hook	N/A
Clearance Date	N/A	09-01-2009	N/A
Classification / Regulation	Class 2 / 878.4400	Class 2 / 876.1500	Equivalent
Product Code	GEI	GCJ	Equivalent
Intended for	Prescription Use	Prescription Use	Same
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.	The SILS^{TM} L-Hook* single use articulating hook with monopolar cautery has application in endoscopic, gynecological, and general abdominal and thoracic laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery.	Equivalent

510(k) Summary

Principles of operation	It 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 end-tip (hook or spatula type), Φ8 diameter shaft, grip part, and electrosurgical unit connection electrode plug. During a procedure with this product, the end-tip is bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the end-tip can also turn 360° when rotating the grip.	SILS Hand instrument contains a pistol grip, a rigid shaft with an articulating and rotating end effector, and opposing jaws or an electrocautery hook at the distal end. The SILS Hook single use articulating hook with monopolar cautery has application in endoscopic, gynecological, and general abdominal and thoracic laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery. The hook administer electrocautery. The end effector of the instrument articulates when the handle is deflected relative to the shaft and rotates when a rotation wheel is turned.	N/A
Energy Type	Radiofrequency	Radiofrequency	Same
Electrode type (monopolar or bipolar)	Monopolar	Monopolar	Same
End-tip type	Hook, Spatula	Hook	Same
Physical dimensions and design (size, length)	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 5mm - Shaft Length: 360mm, 460mm	Different (Shaft diameter of the proposed device is the same as reference predicated device (K190909). The risk analysis for shaft diameter and length has been completed)
Rated voltage	3,933Vp	Not found	N/A
Materials (electrode)	Stainless steel	Not found	N/A
Materials (insulation)	Polyetherimide / Zirconia	Not found	N/A
Materials (Shaft)	Glass fiber	Not found	N/A
Articulating feature	Pitch:±80° or more, Yaw:±80° or more and Open-Close	Pitch:±80° Yaw:±80	Same
Sterilization	EO	EO	Same

510(k) Summary

Table 6.2 Reference Predicate Device

	Proposed device	**Reference Predicate Device 1**	**Reference Predicate Device 2**	**Equivalence**
510(K) Number	In process	K190909	K142868	N/A
Manufacture	LivsMed, Inc.	LivsMed, Inc.	Purple Surgical International Limited	N/A
Device Name	ArtiSential Laparoscopic Instruments-Electrodes	ArtiSential Bipolar Fenestrated Forceps	Laparoscopic Electrodes & Monopolar cables	N/A
Clearance Date	N/A	02-13-2020	11-21-2014	N/A
Classification / Regulation	Class 2 / 878.4400	Class 2 / 878.4400	Class 2 / 878.4400	Equivalent
Product Code	GEI	GEI	GEI	Equivalent
Intended for	Prescription Use	Prescription Use	Prescription Use	Same
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.	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.	use in general laparoscopic surgery requiring the use of monopolar electrosurgical cutting and/or coagulation	Equivalent
Principles of operation	It 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	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	Not found	N/A

510(k) Summary

	tissues and cause coagulation. It is composed of a end-tip (hook or spatula type), Φ8 diameter shaft, grip part, and electrosurgical unit connection electrode plug. During a procedure with this product, the end-tip is bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the end-tip can also turn 360° when rotating the grip.	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	Same
Electrode type (monopolar or bipolar)	Monopolar	Bipolar	Monopolar	N/A
Physical dimensions and design (size, length)	- Shaft diameter: 8mm - Shaft Length: 250mm, 380mm, 450mm	- Shaft diameter: 8mm - Shaft Length: 380mm	- Shaft diameter: 5mm - Shaft Length: 330mm	Different (Shaft diameter of the proposed device is the same as reference predicated device (K190909). The risk analysis for shaft diameter and length has been completed)

Rated voltage	3,933Vp	200Vp	Not found	N/A
Materials (electrode)	Stainless steel	Stainless steel	Not found	Equivalent
Materials (insulation)	Polyetherimide / Zirconia	Polyetherimide	Not found	Equivalent
Materials (Shaft)	Glass fiber	Glass fiber	Not found	Equivalent
Articulating feature	Pitch:±80° or more, Yaw:±80° or more and Open-Close	Pitch:±80° or more, Yaw:±80° or more and Open-Close	N/A	Equivalent
Tip rotation	360°	360°	Not found	Equivalent
Sterilization	EO	EO	Radiation	Equivalent

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 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, 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. 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 (Appearance, Dimension, Operational test, Tensile strength, Feedthrough test). Thermal effects were also performed, as recommended by the FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, within 3 pigs on Liver, kidney and abdominal muscle tissues. Results demonstrated the subject device can perform the intended use safely and effectively.

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, Monopolar Series indication for use is similar to the predicate device (K091869). The energy type, electrode type, sterilization as well as similar physical characteristics are the same. Although there are some minor differences with each product, these differences between the ArtiSential Monopolar 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, Monopolar Series are considerably similar to the predicate and reference devices 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 and reference devices. 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.