June 5, 2023

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

Re: K230498
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: 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 -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.05 11:54:14 -04'00'

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

A FDA Form 3881 is provided on the following pages.

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)*
K230498

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:

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*"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."*

# 4. 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 |
| 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 |
|---|---|---|
| LivsMed Inc. | ArtiSential Laparoscopic Instrument-Electrodes | K200501 |

## 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** |
|---|---|---|
| 510(K) Number | K230498 | K200501 |
| Manufacture | LivsMed, Inc. | LivsMed, Inc. |
| Device Name | ArtiSential Laparoscopic Instruments-Electrodes | ArtiSential Laparoscopic Instruments-Electrodes |
| Clearance Date | N/A | 11-05-2020 |
| Classification / Regulation | Class 2 / 878.4400 | Class 2 / 878.4400 |
| Product Code | GEI | GEI |
| Intended for | Prescription Use | Prescription Use |
| 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. | ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series are indicated for cutting and coagulation in endoscopic, gynecological, and general abdominal and thoracic and general laparoscopic procedures. |
| 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. | 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. | 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. |
| Energy Type | Radiofrequency | Radiofrequency |
| Electrode type (monopolar or bipolar) | Monopolar | Monopolar |
| End-tip type | Hook, Spatula | Hook, Spatula |
| Physical dimensions and design (size, length) | - Shaft diameter: 8mm<br><br>- Shaft Length: 250mm, 380mm, 450mm | - Shaft diameter: 8mm<br><br>- Shaft Length: 250mm, 380mm, 450mm |
| Rated voltage | 3,933Vp | 3,933Vp |
| Materials (electrode) | Stainless steel | Stainless steel |
| Materials (insulation) | Zirconia / Teflon | Polyetherimide / Zirconia |
| 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 |
| Sterilization | 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, 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 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

| Test clause and Test requirement | Test specification | Results- Remarks |
|---|---|---|
| 1. Appearance<br>There should be no defects in the appearance of the product and there should be no problem in use. | Visual observation | No crack, stain or no substances on the surface of the product |
| 2. Dimension<br>It shall be within ± 5% of the indicated value of the dimensional term. | Measure by Vernier calipers and dial gauge etc. | Pass<br>Refer to [Test result] on 8-37 page at attachment #11 |
| 3. Operational test<br>The end-tip and hub can be bent up, down, left, and right a range of above ±80° and are capable of 360° rotation. | Adjusting the end-tip by manipulating the grip and control ring and measure the angle at bending and turning. | The end-tip and hub are bent up, down, left and right within above 80° and can rotate 360°. |
| 4. Tensile strength<br>The end-tip and shaft connections shall not be damaged from pulling of 20 N. | Hold the end-tip and shaft connections respectively and apply a force of 20 N using Push pull gauge. | No damage to the connection when applying a force of 20N |
| 5. Feedthrough test<br>Electricity should be transmitted between the electrode tip and the connector. | Electrical conduction between the electrode tip and the connector is tested using a DMM (digital multi meter). | The resistance value between the electrode tip and the connector is less than 1Ω |

The device had passed all performed tests.

Thermal effects on tissue were also tested. Please refer to attachment 16.
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 same to the predicate device (K200501). 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.