June 6, 2024

LivsMed Inc.
Hyeonbin Chung
Assistant Manager
304, D-dong, 700, Pangyo-ro, Bundang-gu
Seongnam-si, Gyeonggi-do 13516
Korea, South

Re: K240657

Trade/Device Name: ArtiSential Laparoscopic Instruments-Electrodes (AMHD01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01L-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01-FH); ArtiSenti

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 8, 2024
Received: March 8, 2024

Dear Hyeonbin Chung:

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 (the 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

available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.06.06 07:44:33 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

N/A K240657

Device Name

ArtiSential Laparoscopic Instruments-Electrodes (AMHD01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHD01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHD01L-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHD01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHD01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHD01L-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHU01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHU01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHU01L-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHU01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHU01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHU01L-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHL01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHL01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHL01L-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHL01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHL01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHL01L-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHR01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHR01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHR01L-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHR01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHR01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMHR01L-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMT01-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMT01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMT01L-LH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMT01-LH);

ArtiSential Laparoscopic Instruments-Electrodes (5AMT01S-LH);
ArtiSential Laparoscopic Instruments-Electrodes (AMT01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMT01S-FH);
ArtiSential Laparoscopic Instruments-Electrodes (AMT01L-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMT01-FH);
ArtiSential Laparoscopic Instruments-Electrodes (5AMT01S-FH)

Indications for Use *(Describe)*

ArtiSential Laparoscopic Instruments-Electrodes, Monopolar Series (Hand-controlled) 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.

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510(k) Summary

Prepared on: 2024-03-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	LivsMed Inc.
Applicant Address	304, D-dong, 700, Pangyo-ro, Bundang-gu Seongnam-si Gyeonggi-do 13516 Korea, South
Applicant Contact Telephone	82 10-2381-8195
Applicant Contact	Ms. HYEONBIN CHUNG
Applicant Contact Email	hyeonb@livsmed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ArtiSential Laparoscopic Instruments-Electrodes (AMHD01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHD01L-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHD01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHU01L-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHU01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHL01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHL01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHL01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHL01-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHL01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHL01L-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHL01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHR01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHR01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMHR01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01-LH);

	ArtiSential Laparoscopic Instruments-Electrodes (AMHR01-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHR01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMHR01L-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMHR01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMT01-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMT01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMT01L-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMT01-LH); ArtiSential Laparoscopic Instruments-Electrodes (5AMT01S-LH); ArtiSential Laparoscopic Instruments-Electrodes (AMT01-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMT01S-FH); ArtiSential Laparoscopic Instruments-Electrodes (AMT01L-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMT01-FH); ArtiSential Laparoscopic Instruments-Electrodes (5AMT01S-FH)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code	GEI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230498	ArtiSential Laparoscopic Instruments-Electrodes	GEI

Device Description Summary

21 CFR 807.92(a)(4)

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, Φ5, Φ8 diameter shaft, grip part, and electrosurgical unit connection electrode plug.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use is the same with Predicate device(K230498)

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

Technological Comparison

21 CFR 807.92(a)(6)

ArtiSential Laparoscopic Instruments-Electrodes uses the principle of applying high-frequency currents from the electrode to the human body to generate heat by bio-impedance 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), Φ5, Φ8 diameter shaft, grip part, and COAG/CUT button, cable and connector. COAG/

CUT button, cable and connector are different from predicate device(K230498).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Thermal spread testing was performed in accordance with the FDA guidance.
Trocar Compatibility Testing was performed in accordance with FDA Usability guidance.