November 15, 2024

LivsMed Inc.
% Dave Yungvirt
Official Contact Person
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K241138
Trade/Device Name: ArtiSeal Vessel Sealing System-ArtiSeal Instruments; ArtiSeal Vessel Sealing System-ArtiSeal Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 13, 2024
Received: November 15, 2024

Dear Dave Yungvirt:

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: 2024.11.15 14:31:04 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241138

Device Name
ArtiSeal Vessel Sealing System - ArtiSeal Instruments
ArtiSeal Vessel Sealing System - ArtiSeal Generator

Indications for Use *(Describe)*

ArtiSeal Vessel Sealing System-ArtiSeal Instruments

ArtiSeal Vessel Sealing System - ArtiSeal Instruments are a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation (sealing) and division (Cutting) of vessels and tissue bundles is desired. ArtiSeal Vessel Sealing System - ArtiSeal Instruments can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery.

ArtiSeal Vessel Sealing System-ArtiSeal Generator

The ArtiSeal Vessel Sealing System - ArtiSeal Generator is a high-frequency electrosurgical device used in conjunction with disposable hand-controlled electrosurgical instruments, known as ArtiSeal Instruments. It provides radiofrequency (RF) energy to ligate vessels and tissue bundles. This energy platform automatically detects the connected instrument and immediately performs safety and diagnostic functions for the instrument. It is indicated for use in general surgery.

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.

510(k) Summary - K241138

Contact Details

Applicant Name : LivsMed Inc.

Applicant Address : 304, D-dong, 700, Pangyo-ro, Bundang-gu, Seongnam-si, Gyenggi-do, 13516, Republic of Korea

Applicant Contact Telephone : +82 70 7708 1399

Applicant Contact : Hera Park

Applicant Contact Email : hera@livsmed.com

Device Name

Device Trade Name:

ArtiSeal Vessel Sealing System - ArtiSeal Instruments

ArtiSeal Vessel Sealing System - ArtiSeal Generator

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

Predicate device : K162941/Ligasure Blunt Tip, Sealer/Divider, Nano-coated/GEI

Predicate device : K181389/Valleylab FT10 Energy Platform, Valleylab FX8 FX Series Energy Platform/GEI

Device Description Summary

ArtiSeal Vessel Sealing System - ArtiSeal Instruments

The ArtiSeal Vessel Sealing System - ArtiSeal instruments are sterile, single-use, invasive instruments which are used with electrosurgical generator(ArtiSeal Generator), intended to be used during laparoscopic/minimally invasive or open surgical procedures where ligation and division of vessels and tissue bundles is desired.

When activating the sealing button of ArtiSeal Vessel Sealing System-ArtiSeal instruments, the ArtiSeal Generator applies a high frequency (RF) energy to the electrode portion of the jaw. Heat is generated from the electrode for ligation.

During a procedure with this product, the jaw opens if the grip lever opens, and jaw closes if the grip lever pulled. 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.

ArtiSeal Vessel Sealing System - ArtiSeal Generator

The ArtiSeal Vessel Sealing System - ArtiSeal Generator supplies RF energy to the ArtiSeal Instruments. This energy supply device uses a touchscreen interface and features a unique instrument connection socket for connecting the ArtiSeal Instrument.
By connecting the connector on the ArtiSeal Instrument to the instrument connection socket, the energy supply device can provide energy to the electrode.

Indications for Use

ArtiSeal Vessel Sealing System - ArtiSeal Instruments

ArtiSeal Vessel Sealing System - ArtiSeal Instruments are a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation (sealing) and division (Cutting) of vessels and tissue bundles is desired. ArtiSeal Vessel Sealing System - ArtiSeal Instruments can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery.

ArtiSeal Vessel Sealing System - ArtiSeal Generator

The ArtiSeal Vessel Sealing System - ArtiSeal Generator is a high-frequency electrosurgical device used in conjunction with disposable hand-controlled electrosurgical instruments, known as ArtiSeal Instruments. It provides radiofrequency (RF) energy to ligate vessels and tissue bundles. This energy platform automatically detects the connected instrument and immediately performs safety and diagnostic functions for the instrument. It is indicated for use in general surgery.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Tested to verify equivalent performance with similar devices (Ligasure Blunt Tip, Sealer/Divider, Nano-coated), complete vessel sealing was achieved without rebleeding as well as problematic macroscopic and microscopic complications. The purpose of this study was to evaluate the vessel sealing performance and tissue effects of ArtiSeal Instruments and ArtiSeal Generator. The evaluations included the device's ability to seal vessels of various sizes and types, its effect on tissue damage, as well as the device's safety and efficacy. The study involved sealing(ligation) and cutting(dividing) of some blood vessels and tissue bundles in pigs, along with the evaluation of sealing quality parameters such as tissue adhesion, carbonization, transparency, desiccation, and damage to adjacent tissue.

As a result of clinical observation, no dead animals were observed during the entire experiment period, and no abnormal symptoms related to the application of the test device were observed.