



October 21, 2025

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

Re: K250126

Trade/Device Name: ArtiSeal Vessel Sealing System - ArtiSeal Instruments (AS01M)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 22, 2025
Received: September 22, 2025

Dear Dong Wook 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

**Colin K.
Chen -S**  Digitally signed by
Colin K. Chen -S
Date: 2025.10.21
17:09:18 -04'00'

Colin K. Chen, Ph.D.
Acting 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

Indications for Use

Submission Number (if known)

K250126

Device Name

ArtiSeal Vessel Sealing System - ArtiSeal Instruments (AS01M)

Indications for Use (Describe)

ArtiSeal Vessel Sealing System - ArtiSeal Instruments are a bipolar electrosurgical instrument intended for use only with the ArtiSeal Generator 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.

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 - K250126

October 20, 2025

Contact Details

Applicant Name: LivsMed Inc.

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

Applicant Contact Telephone: +82 70 7708 1399

Applicant Contact: Dong Wook Lee

Applicant Contact Email: hera@livsmed.com

Device Name

Device Trade Name: ArtiSeal Vessel Sealing System - ArtiSeal Instruments (AS01M);

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: K241138 / ArtiSeal Vessel Sealing System - ArtiSeal Instruments, ArtiSeal Vessel Sealing System - ArtiSeal Generator

Device Description Summary

The ArtiSeal Vessel Sealing System - ArtiSeal Instruments (AS01M) is a sterile, single-use, invasive instrument which is 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 radiofrequency (RF) energy to the electrode portion of the jaw. Heat is generated from the electrode for ligation.

During surgical procedures, the user operates the grip lever to open and close the jaw. Furthermore, the jaw can be bent up, down, left, and right within a range of up to $\pm 90^\circ$ or more by adjusting the grip accordingly. The jaw also provides 360° articulation (rotation) by turning the grip.

Indications for Use

ArtiSeal Vessel Sealing System - ArtiSeal Instruments are a bipolar electrosurgical instrument intended for use only with the ArtiSeal Generator 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.

Nonclinical Testing Summary

A nonclinical program determined that the subject and predicate devices are substantially equivalent in performance and safety.

- **Bench Testing:**
Evaluated mechanical and electrical performance (jaw force, jaw gap, jaw hyper-extension, grasping force, device cycle, and electrical properties including inductance, capacitance, and resistance). Results were consistent with the predicate device and met all acceptance criteria.
- **Ex Vivo Burst Pressure Testing:**
Mean burst pressure of sealed vessels exceeded 240 mmHg across all vessel sizes, with no statistically significant differences from the predicate.
- **Acute Thermal Spread Study:**
Thermal spread remained below 2 mm with seal quality scores ≤ 2 , meeting predefined acceptance limits.
- **21-Day Chronic Survival Study:**
Long-term tissue healing and seal integrity were equivalent to the predicate, with no rebleeding or adverse histological findings.

These results demonstrate equivalent mechanical performance, vessel sealing effectiveness, and tissue safety.

Biocompatibility

All patient-contacting materials are identical to those used in the predicate device.

Testing in accordance with ISO 10993-1 and related standards, including cytotoxicity, hemolysis, irritation, sensitization, systemic toxicity, pyrogenicity, and material characterization, confirmed that all materials are biocompatible and substantially equivalent to the predicate device.

Sterilization, Packaging, and Shelf Life

The device is sterilized by ethylene oxide (EO) in accordance with ISO 11135, achieving a Sterility Assurance Level (SAL) of 10^{-6} .

Packaging validation in accordance with ISO 11607-1 and ISO 11607-2 confirmed seal integrity and sterile barrier performance, and accelerated and real-time aging verified a three-year shelf life consistent with the predicate device.

Electromagnetic Compatibility and Electrical Safety

The device operates with the same ArtiSeal Generator as the predicate.

Testing per IEC 60601-1, 60601-1-2, and 60601-2-2 demonstrated compliance with applicable electrical safety and EMC standards.

Substantial Equivalence Comparison

Characteristic	Proposed Subject Device (AS01M)	Predicate Device (AS01L, K241138)	Comparison
Manufacturer	LivsMed Inc.	LivsMed Inc.	Same

Device Classification / Regulation	Class II / 21 CFR 878.4400	Class II / 21 CFR 878.4400	Same
Product Code	GEI	GEI	Same
Indications for Use	ArtiSeal Vessel Sealing System - ArtiSeal Instruments are a bipolar electrosurgical instrument intended for use only with the ArtiSeal Generator 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 Instruments are a bipolar electrosurgical instrument intended for use only with the ArtiSeal Generator 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.	Same
Principle of Operation	Bipolar RF energy applied via electrodes to seal and divide tissue	Bipolar RF energy applied via electrodes to seal and divide tissue	Same
Energy Type	Bipolar Radiofrequency	Bipolar Radiofrequency	Same
Biocompatibility	Evaluated per ISO 10993-1	Evaluated per ISO 10993-1	Same
Sterilization Method	EO gas (SAL 10 ⁻⁶), single-use	EO gas (SAL 10 ⁻⁶), single-use	Same
Shaft Dimensions	Ø8 mm × 345 mm	Ø8 mm × 415 mm	Similar
Performance	Equivalent jaw force, sealing performance, and electrical characteristics verified through bench and animal testing	Equivalent jaw force, sealing performance, and electrical characteristics verified through bench and animal testing	Equivalent
Electrical Safety / EMC	Compliant with IEC 60601-1, -1-2, -2-2	Compliant with IEC 60601-1, -1-2, -2-2	Same

Conclusion

The ArtiSeal Vessel Sealing System - ArtiSeal Instruments (AS01M) and the predicate device (AS01L) are identical in intended use, operating principle, energy type, electrode configuration, and materials, with the only difference being shaft length.

Performance validation/verification, including bench testing, ex vivo burst pressure, acute and chronic in vivo studies, biocompatibility, sterilization, and electrical safety, demonstrates that the subject device meets all predefined acceptance criteria and performs equivalently to the predicate.

Therefore, the ArtiSeal Vessel Sealing System - ArtiSeal Instruments (AS01M) is substantially equivalent to the legally marketed predicate device (K241138) and is as safe and effective for its intended clinical use.