October 16, 2022

Aesthetics Biomedical
Lawrence Rheins
Chief Scientific Officer
4602 North 16th Street, Suite 300
Phoenix, Arizona 85016

Re: K221574
Trade/Device Name: LUDWIG Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, IYO
Dated: September 13, 2022
Received: September 19, 2022

Dear Lawrence Rheins:

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,

for

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)*

K221574

Device Name
LUDWIG Electrosurgical System

Indications for Use *(Describe)*
The LUDWIG Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

SPONSOR INFORMATION

Name: Aesthetics Biomedical
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Phone: (800) 726-5029

Official Correspondent:

Name: Lawrence A. Rheins
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Phoenix, AZ 85016
Phone: (760)877-5385
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FDA Establishment Reg. No.: 3012204368

Date Prepared: October 14, 2022

DEVICE NAME

Trade Name:	LUDWIG Electrosurgical System
Common Name:	Electrosurgical System and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Number:	21 CFR 878.4400 (Class II)
Product Code:	GEI, IYO
Classification Panel:	General and Plastic Surgery

PREDICATE DEVICE

The LUDWIG Electrosurgical System is substantially equivalent to the Potenza Device (primary predicate), K192545 and the Genius Device (reference predicate), K180945.

INTENDED USE

The LUDWIG Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

DEVICE DESCRIPTION

The LUDWIG Electrosurgical System is comprised of the following components:

- The system's main body, which consists of:
  - Touch-screen control/display panel
  - High radio frequency (RF)-generating output component at 0.5, 1 or 2 MHz
  - RF Handpiece for transfer of energy to human tissue
  - Ultrasound Handpiece for visualization of dermis and epidermis
  - Disposable bipolar micro-needle cartridge (electrode) that is inserted into RF Handpiece and used for coagulation of human tissue
  - Power cord

The LUDWIG Electrosurgical System generates radiofrequency (RF) energy by means of high RF at .5 MHz, 1MHz or 2MHz. The RF energy is delivered through the skin into the target tissue via a handpiece equipped with an electrode tip. As the RF energy passes through the tissue, it generates an electrothermal reaction which is capable of coagulating the tissue.

TECHNOLOGICAL CHARACTERISTICS

The LUDWIG Electrosurgical Device and its predicate devices operate in the same manner by applying RF bipolar current via the microneedle electrode assembly to the dermis to produce controlled zones of coagulated collagen at low temperatures without damaging the epidermis layer.

PERFORMANCE DATA

To establish safety and efficacy of the LUDWIG Electrosurgical System, the following evaluations were completed following the below standards and FDA guidance documents. All acceptance criteria were met:

- **Electrical Testing per:**
  - IEC 60601-1:2005/(R)2012, A1:2012
  - IEC 60601-1-2:2014, Ed. 4.0
  - IEC 60101-2-2:2017, Ed. 6.0
  - IEC 60601-1-6:2010 +A1 2013
  - IEC 62366:2007/AMD 1:2014
- **Biocompatibility Testing per:**
  - ISO 10993-1:2009
  - ISO 10993-5:2009
  - ISO 10993-10:2010
  - ISO 10993-11:2017/USP <151>
- **Sterility Testing:**
  - The micro-needle cartridge is supplied sterile and sterility conforms to a Sterility Assurance Level (SAL) of 10^{-6}:
    - ISO 11135:2014
    - ISO 11138-7:2019
    - ISO 10993-7:2008
- **Shelf Life and Packaging Testing per:**
  - ASTM F1980-16
  - ASTM F1929-15
  - ASTM F88/F88M-15
- **Ultrasound Testing per:**
  - IEC 60601-2-37 (Edition 2.1, 2015)
  - IEC 62359 (Edition 2.1 2017-09)
- **Software Verification and Validation Testing:**
  - FDA's Draft Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices",* issued November 4, 2021.
- **Thermal Testing:**
  - FDA's Guidance for Industry and FDA Staff *"Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"*, issued March 9, 2020.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The below table summarizes the key elements of the subject device and each predicate device, supporting substantial equivalence:

	Proposed: ***LUDWIG***	**Primary Predicate:** ***Potenza*** ***K192545***	**Reference Predicate:** ***Genius*** **K180945**
Manufacturer	**Aesthetics Biomedical, Inc**	**Jeisys Medical, Inc**	**Lutronic Corporation**
Classification	Class II 21 CFR §878.4400	Class II 21 CFR §878.4400	Class II 21 CFR §878.4400
Product Code	**GEI**-Electrosurgical, Cutting & Coagulation & Accessories **OUH**-Skin Resurfacing Rf Applicator **IYO**-System, Imaging, Pulsed Echo, Ultrasonic	**GEI**- Electrosurgical, Cutting & Coagulation & Accessories **OUH** - Skin Resurfacing Rf Applicator	**GEI**- Electrosurgical, Cutting & Coagulation & Accessories
Intended Use	The LUDWIG Electrosurgical System is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The LUTRONIC GENIUS Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
User Interface	Color Touch Panel	Color Touch Panel	Color Touch Panel
Electrical Requirements	100-240 VAC, 50-60 HZ	100-240 VAC, 50-60 HZ	100-240 VAC, 50-60 HZ
RF FEATURES			
Frequency	**Radiofrequency:** 0.5 MHz, 1MHz, 2MHz	**Radiofrequency:** 1 MHz, 2MHz	**Radiofrequency**: 0.5MHz
Mode	Bipolar	Bipolar and Monopolar	Bipolar
Max Power	Max 50W	Max 50W	Max 50W
RF Connected Handpiece	1 RF handpiece	2 RF handpieces	RF handpiece
RF NEEDLE FEATURES			
Number of Needle Cartridges	6 different electrode tips	6 different electrode tips	4 different electrode tips
Needle Material	Stainless Steel	Stainless Steel	Stainless Steel
Needle Extension	0.5 - 4mm (0.1 step)	0.5-4mm (0.1 step)	0.5 - 3.5mm (0.1 step)

CONCLUSION

The subject LUDWIG Electrosurgical System has the same intended use and similar indications, technological characteristics, and principles of operation as its primary predicate (K192545) and reference device (K180945). The technological differences between the subject device and its predicate device raise no new issues of safety or effectiveness. Non-clinical and animal testing was conducted to evaluate the performance of subject device in comparison to the predicate devices and results have demonstrated substantial equivalence of the subject device to the predicates in terms of safety and effectiveness for the intended use.