August 14, 2023

Jeisys Medical Inc.
% Sanghwa Myung
Regulatory Affairs Consultant
E&m
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Korea, South

Re: K230663
Trade/Device Name: Density
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 14, 2023
Received: July 14, 2023

Dear Sanghwa Myung:

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: 2023.08.14 14:21:44 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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Enclosure

5. Indication for use

See next 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)*
K230663

Device Name
DENSITY

Indications for Use *(Describe)*
DENSITY indicated 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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6. 510(k) Summary

K230663

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

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Primary Contact: Sanghwa Myung

Date 510(k) summary Prepared: July 14, 2023

Trade Name: DENSITY

Common Name: Electrosurgical Device
Classification: II
Product Code: GEI
Regulation Numbers: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation
Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]
Review Panel: General & Plastic Surgery (ODE)

Description of Device:

The DENSITY generates radiofrequency (RF) energy by means of high RF at 6.78MHz. 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. In detail, the main body uses the "reverse thermal gradient" principle to deliver RF energy, and thus, heat is generated and selective coagulation occurs while cooling the epidermis, resulting in denaturation and contraction of collagen fibers.

The DENSITY is an RF (radiofrequency), software-controlled electrosurgical device used for electrocoagulation of soft tissue and hemostasis.

The DENSITY consists of the following components:

- Electrosurgical Unit - Main body

•Handpiece

•6 different electrode tips

•Neutral electrode pad and neutral electrode pad cable, cleared under K201685

•Foot switch

•Power cord

Indication for use:

DENSITY indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Predicate Device:

Predicate Devices	K170758 Applicant: Solta Medical, Inc Trade/Device Name: Thermage FLX System Regulation Number: 21 CFR 878.4400 Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories Regulatory Class: Class II Product Code: GEI, ISA

Substantial Equivalence:

Comparison table is as follows.

Table 1: Substantial equivalence comparison

	Proposed Device	Predicate Device
510(k) Number	Pending	K170758
Manufacturer	Jeisys	So;ta Medical, Inc
Trade/Device Name	DENSITY	Thermage FLX System
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indication for use	DENSITY indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The radiofrequency-energy only delivery components of the Thermage FLX System are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
Output energy type	Radio Frequency	Radio Frequency
User interface	Color Touch Panel	Color Touch Panel
Operating Frequency	6.78MHz	6.78MHz
Max Power	400 W	400W
Electrode tip	3 types (0.25 cm^2, 4 cm^2,	4 types (0.25 cm^2, 3.0 cm^2,

	16cm^2)	4 cm^2, 16cm^2)
Coolant solution	Cryogen	Cryogen
Temperature range	65~75℃	65~75℃
RF Time	50 ~ 800 ms	50 ~ 1000 ms
Impedance	75 - 400 Ω	75 - 400 Ω
Communication to generator	LCD touch screen	LCD touch screen
Style of electrode tip	Monopolar, Bipolar	Monopolar
Number of active electrodes per applicator	Number of output patterns - I-Tip(Around eye) I, F-Tip(Face): 1ea - I-Tip II(Around eye), F-Tip II(Face): 2ea - B-Tip(Body), B-Tip(Body) II: 4ea	Number of output patterns - EYE Tip 0.25: 1ea - TOTAL Tip 3.0: 1ea - NEW TOTAL TIP 4.0: 1ea - BODY TIP 16.0: 4ea
Coolant control parameters (valve type; valve activation, power supply, solution)	Type of gas: 1234ze Method of gas control: Handpiece solenoid control operation Mouth valve specifications: 12V Solenoid valve specifications: 1.8V 24.8 BAR	Type of gas: 1234ze Method of gas control: Handpiece solenoid control operation Mouth valve specifications: 12V Solenoid valve specifications: 1.8V 24.8 BAR

- Discussion

- Electrosurgical Unit:
- Operating frequency of 6.78 MHz: ***same*** as for the predicate device.
- Max power, ***same*** as for the predicate device.
- Electrode tip: our device's tip types are including the predicate device.
- Temperature range: ***same*** as for the predicate device.
- Impedance: ***same*** as for the predicate device.
- Coolant solution: ***same*** as the reference device.
- Style of electrode tip: Subject device have two type of electrode tip that is monopolar and bipolar. Predicate device is monopolar type. This mode difference should not affect performance or safety.
- Different #1 Subject device and predicate device are divided into types of TIP depending on the area to be applied. This difference does not affect performance or safety.
- Coolant control parameters: DENSITY and predicate devices have the same parameters, but the exact technical specifications are unknown.

There are no significant differences between DENSITY and the predicate devices (K170758) that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics

Non-clinical Performance Data:

-. Basic safety and essential performance of the DENSITY is evaluated in accordance with IEC 60601-1:2005/AMDI:2012

-. Effect to the device by electromagnetic disturbances is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-2:2014.

-. Medical electrical equipment – Part 2 -2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, IEC 60601-2-2

-. General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-6:2013.

-. The software for DENSITY is verified and validated in accordance with its moderate level of concern. Software life cycle processes are evaluated according to the FDA-recognized consensus standard, IEC 62304:2006.

-. Application of usability engineering to medical devices is evaluated in accordance with IEC 62366:2008 based on Human Factor Engineering

-. Biocompatibility of DENSITY is documented in the reference of ISO 10993-1:2009, ISO 10993-5:2009, and 10993-10:2010.

Risk Management

A risk analysis was conducted based on ISO 14971:2012 Medical devices – Application of risk management to medical devices

Clinical Data:

No clinical performance testing was performed.

Conclusion

Subject device is substantially equivalent to its predicate devices with same indication for use and technological characteristics. Any minor differences in the human interface and accessories design do not raise any new types of safety and effectiveness issues, as verified by performance testing. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that we conclude that substantially equivalent with predicate device.