July 8, 2025

Jeisys Medical Incorporated
% Sanghwa Myung
Regulatory Affair Specialist
E&m
D1474, PyeongCheon Arco Tower, 230, Simin-Daro, Dongan-gu
Anyangsi, Gyeonggi 14067
Korea, South

Re: K250065
Trade/Device Name: DENSITY; DENZA; DENSITY Noir
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 9, 2025
Received: January 10, 2025

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 (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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.07.08 14:50:03 -04'00'

James Jang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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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.

510(k) Number *(if known)*
K250065

Device Name
DENSITY;
DENZA;
DENSITY Noir

Indications for Use *(Describe)*
This device 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.

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510(k) Summary

K250065

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 4th, 2025

Trade Name: DENSITY, DENZA, DENSITY Noir

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, DENZA, DENSITY Noir 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 devices are an RF (radiofrequency), software-controlled electrosurgical device used for electrocoagulation of soft tissue and hemostasis.

It consists of the following components:

- Electrosurgical Unit - Main body

•Handpiece

•electrode tips

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

•Foot switch

•Power cord

Indication for use:

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

Predicate Device:

Predicate Devices	K230663 Applicant: Jeisys Medical Inc 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

Substantial Equivalence:

Comparison table is as follows.

Table 1: Substantial equivalence comparison

	Proposed Device	Predicate Device	**Comparison Comment**
510(k) Number	K250065	K230663	-
Manufacturer	Jeisys Medical Inc	Jeisys Medical Inc	-
Trade/Device Name	DENSITY, DENZA, DENSITY Noir	DENSITY	-
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Substantial Equivalence
Indication for use	This device indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	DENSITY indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Substantial Equivalence
Output energy type	Radio Frequency	Radio Frequency	Substantial Equivalence
User interface	Color Touch Panel	Color Touch Panel	Substantial Equivalence
Operating Frequency	6.78MHz	6.78MHz	Substantial Equivalence
Max Power	400 W	400 W	Substantial

			Equivalence
Type of electrode tips	3 types (0.25 cm^2, 4 cm^2, 16cm^2)	3 types (0.25 cm^2, 4 cm^2, 16cm^2)	Substantial Equivalence
Coolant solution	Cryogen	Cryogen	Substantial Equivalence
Temperature range	65~75℃	65~75℃	Substantial Equivalence
RF Time	50 ~ 800 ms	50 ~ 800 ms	Substantial Equivalence
Impedance	75 - 400 Ω	75 - 400 Ω	Substantial Equivalence
Communication to generator	LCD touch screen	LCD touch screen	Substantial Equivalence
Style of electrode tip	Monopolar, Bipolar	Monopolar, Bipolar	Substantial Equivalence
Number and name of electrode tips	I-Tip, Classic-E Tip, B-Tip, Classic-B Tip, F-Tip, Classic-F Tip, I-Tip II, High-E Tip, F-Tip II, High-F Tip, High-B Tip, ALPHA Tip, B-Tip II (Total 13 Tips)	I-Tip, I-Tip II, B-Tip, B-Tip II, F-Tip, F-Tip II (Total 6 Tips)	Deferent #1
Coolant control parameters (valve type; valve activation, power supply, solution)	1)Type of gas: 1234ze 2)Method of gas Control: Handpiece solenoid control operation 3)Mouth valve specifications: 12V 4)Solenoid valve specifications: 1.8V 24.8 BAR	1)Type of gas: 1234ze 2)Method of gas Control: Handpiece solenoid control operation 3)Mouth valve specifications: 12V 4)Solenoid valve specifications: 1.8V 24.8 BAR	Substantial Equivalence

- 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 7 new tips added and the tips only different is film design. 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.

Subject device is substantially equivalent to its predicate devices with same indication for use and technological characteristics. The non-clinical data for proposed device, including

biocompatibility, bench testing, hardware, and software documentation shows that the device should perform as intended in the specified use. There are no significant differences between Subject device and the predicate devices (K230663) that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics standards. 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.

Non-clinical Performance Data:

-. Basic safety and essential performance of device was evaluated in accordance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020

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

- Bench testing

Jeisys conducted bench testing to assure that DENSITY, DENZA, DENSITY Noir operates safely and within the predefined design specifications.

- *Ex Vivo* testing conducted on three types of tissue – Tissues choose of under GLP Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", August 15, 2014

Risk Management

A risk analysis was conducted based on ISO 14971:2019 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.