September 8, 2022

Ellusa, LLC
Ms. Suzanne Lucas
Sr. Regulatory Affairs Specialist
2473 Grand Avenue
Baldwin, New York 11510

Re: K222425
Trade/Device Name: Ellusa Reusable Neutral Plates
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 24, 2022
Received: August 11, 2022

Dear Ms. Lucas:

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)*
K222425

Device Name
Ellusa Reusable Neutral Plate

Indications for Use *(Describe)*
The Ellusa Reusable Neutral Plate provides a safe return path for electrosurgical current and is designed for use with Ellusa Generators for minor surgical applications. The Reusable Neutral Plate is provided nonsterile and intended for use only in nonsterile environments.

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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K222425

Exhibit 6. 510(k) SUMMARY

(As required by 21 CFR 807.92(a))

Date Prepared

September 7, 2022

Submitter's Information (807.92(a)(1))

Company Name and Address:
Ellusa, LLC
2473 Grand Avenue
Baldwin, NY 11510
Phone: (516) 634-1370
Establishment Registration #: 3016087306

Contact Information:
Ms. Suzanne Lucas
Sr. Regulatory Affairs Specialist
Phone: (516) 634-1370
Email: slucas@ellusa.com

Device Information (807.92(a)(2))

Trade Name: Ellusa Reusable Neutral Plate

Common/Usual Name: Electrosurgical, Cutting & Coagulation Device & Accessories

Classification Name and Regulation: Electrosurgical Cutting and Coagulation Device and Accessories; 21 CFR 878.4400

Classification Panel: General and Plastic Surgery

Device Class/Product Code
FDA Classification: Class 2
FDA Product Code: GEI

Predicate Devices (807.92(a)(3))

- Ellusa Disposable Neutral Plate (K202562)

K222425

Device Description (807.92(a)(4))
The Ellusa Reusable Neutral Plates will be provided as a flexible plate made of silicone rubber and will be supplied with a 10-foot cable and is non-sterile. There are no differences in the functionality of a reusable neutral plate as compared to the disposable neutral plate. They are both used to provide a safe return path for electrosurgical current.

Intended Use:
The Reusable Neutral Plate provides a safe return path for electrosurgical current and is designed for use with Ellusa RF Generators for minor surgical applications. The Reusable Neutral Plate is provided nonsterile and intended for use only in nonsterile environments.

Substantial Equivalence Comparison (807.92(a)(6))
The Ellusa Reusable Neutral Plate is substantially equivalent in intended use, technological characteristics, operating principle, and performance characteristics to the predicate device by Ellusa (K202562).

Predicate Information	Ellusa Reusable Neutral Plate (SUBJECT DEVICE)	Ellusa Disposable Neutral Plate (K202562 (PREDICATE DEVICE)
Intended Use	The Reusable Neutral Plate provides a safe return path for electrosurgical current and is designed for use with Ellusa Generators for minor surgical applications. The Reusable Neutral Plate is provided nonsterile and intended for use only in nonsterile environments.	The Neutral Plate/Grounding Pad is designed for use with Ellusa Generators and provides a safe return path for electrosurgical current.
Product Code	GEI	GEI
Device Classification	Class II	Class II
Functions	Connect to Electrosurgical Generator to provide safe return path.	Connect to Electrosurgical Generator to provide safe return path.
Operating mode	Monopolar	Monopolar
Energy Source	RF Energy	RF Energy
Cable Length (ft)	10 feet	9 feet
Patient Contacting Materials	Silicone	Silicone
Testing standards used	IEC 60601-2-2 (6th edition)	IEC 60601-2-2 (6th edition)

ellusa LLC.
2473 Grand Avenue, Baldwin, NY 11510
Main: (516) 654-4000 • Fax: (516) 654-8000
www.ellusa.com

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Non-Clinical Testing (807.92(b)(1))

The Reusable Neutral Plates will be manufactured in accordance with the design control requirements of 21 CFR 820.30. Appropriate non-clinical verification and validation activities were planned and conducted to address identified risks and ensure the safety and effectiveness of the device. Testing was conducted for the following standard and resulted in passing results.

- IEC 60601-2-2: 2017 - 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: Cl. 201.8.7.3.101: Thermal effects of HF Leakage Currents
    - IEC 60601-2-2: Cl. 201.8.8.3.103: ACTIVE ACCESSORY HF dielectric strength
    - IEC 60601-2-2: Cl. 201.8.8.3.104: ACTIVE ACCESSORY mains frequency dielectric strength
    - IEC 60601-2-2: Cl. 201.15.101.2: NE cord attachment
    - IEC 60601-2-2: Cl. 201.15.101.4: NE cord insulation
    - IEC 60601-2-2: Cl. 201.15.101.6: NE contact impedance

The reusable neutral plate has been tested and evaluated against the following biocompatibility requirements. All tests resulted in passing results.

- In-Vitro Cytotoxicity ISO 10993-5:2010
- Sensitization ISO 10993-10:2010
- Irritation ISO 10993-10:2010

Technological Characteristics

The devices are substantially equivalent to the predicate device based on a comparison of physical and performance characteristics. They are all intended to be used with electrosurgical generators to provide a safe return path for the electrosurgical current.

Clinical Testing (807.92(b)(2))

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion (807.92(b)(3))

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the similarity to the predicate devices in terms of technology, performance, and indications for use, Ellusa, LLC concludes that the subject device, Ellusa Reusable Neutral Plates do not raise any issues of safety or effectiveness and are substantially equivalent to the predicate device as described above.

ellusa LLC.
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