November 2, 2020

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

Re: K202558
Trade/Device Name: Ellusa Bipolar Wands
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 31, 2020
Received: September 4, 2020

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K202558

Device Name
Ellusa Bipolar Wands

Indications for Use *(Describe)*
The Ellusa Bipolar Wands are intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed.

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

(As required by 21 CFR 807.92(a))

(K202558)

Date Prepared

October 29, 2020

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

Company Name and Address:
Ellusa, LLC
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Phone: (516) 866-0001
www.ellusa.com
Establishment Registration number: 3016087306

Contact Information:

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Sr. Regulatory Affairs Specialist
Phone: (516) 866-0001
Email: slucas@ellusa.com

Device Information (807.92(a)(2))

Trade Name: Ellusa Bipolar Wands

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

Division of General, Restorative, and Neurological Devices

Device Class/Product Code

FDA Classification: Class 2
FDA Product Code: GEI

Predicate Devices (807.92(a)(3))

Soniquence Bipolar Electrodes (K190336)

Use of Guidance Documents

The content provided within this 510k follows the FDA guidance document "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" issued on March 9, 2020.

Device Description (807.92(a)(4))

The Ellusa Bipolar Wand family is a line of disposable bipolar electrosurgical devices which is intended for use by a physician familiar with electrosurgery in bipolar coagulation for general surgery where coagulation of soft tissue is needed. The basic design of the Ellusa Bipolar Wands is a plastic handle, an elongated, insulated electrode shaft, a bipolar electrode tip, and an integrated cable and plug which is designed to connect exclusively to the Ellusa line of high-frequency RF energy sources.

The operational principle of the device is common to all active bipolar electrosurgical devices; the active tip of the Ellusa Bipolar Wand emits RF energy generated according to settings established on the Ellusa Generator which emits high frequency, low temperature radiowaves directed to the electrode tip. The electrical power operating at radio frequency (RF) is transferred to tissue at the surgical site. This energy is capable of cutting or coagulating target tissue depending on the waveform associated with the mode and power setting of the generator. The devices are disposable and intended for single use only. The devices are intended for transient contact with the patient and are provided sterilized by ethylene oxide and has a shelf life of three years from the date of sterilization.

Intended Use:

The Ellusa Bipolar Wands are intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed.

Comparison of Technological Characteristics (807.92(a)(6))

The Ellusa Bipolar Wands are identical in technological characteristics to the Soniquence Bipolar Electrodes (K190336) based on a comparison of physical and performance characteristics. There are no technological differences between the subject device as compared to the predicate devices, and the indications for use are identical.

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Technological Characteristic	Soniquence Bipolar Electrodes PREDICATE DEVICE (K190336)	Ellusa Bipolar Wand SUBJECT DEVICE
Intended Use	The Soniquence Bipolar Electrode is intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed.	The Ellusa Bipolar Wands are intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed.
Product Code	GEI	Identical to predicate
Device Classification	Class II	Identical to predicate
Functions	Cutting/coagulation	Identical to predicate
Operating principle	Bipolar	Identical to predicate
Energy Source	RF Energy	Identical to predicate
Electrode Materials	Stainless steel	Identical to predicate
Tip Configurations	Ball Tip, Standard, Hex blade	Identical to predicate
Tip dimensions	0.5 - 8mm	Identical to predicate
Shaft lengths	11 – 40cm	Identical to predicate
Shaft diameter	1.2 – 6mm	Identical to predicate
Stability and Shelf Life	3 years	Identical to predicate
Coating	None	Identical to predicate
Cable Length (m)	3m	Identical to predicate
Activation Method	Footswtich	Identical to predicate
Testing standards used	IEC 60601-1 and IEC 60601-2-2	Identical to predicate
Biocompatibility	ISO 10993	Identical to predicate
Sterilization Methods	Ethylene Oxide	Identical to predicate
Packaging	Sterile, Blister Tray	Identical to predicate
Min., Max., Default output Values (Wattage)	0-170	Identical to predicate

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

The Ellusa Bipolar Wands 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. The following standards have been applied to the devices and passed all applicable tests requirements.

- IEC 60601-1:2005/(R)2012 and A1:2012 - Medical Electrical Equipment, Part l: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 (Third Edition) + A1 2013: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366:2007 (First Edition) + A1:2014: Medical devices – Application of usability engineering to medical devices
- IEC 60601-1-2:2014 - Medical Electrical Equipment, Part l-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility
- IEC 60601-2-2: 2017 6th edition- 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

Sterilization:

- ISO 11135:2014 - Sterilization of health-care products — Ethylene oxide —Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1: 2018 Sterilization of medical products--Microbiological methods--Part 1: Determination of population of microorganisms on product
- ISO 11737-2: 2019 Sterilization of medical devices--Microbiological methods--Part 2: Tests of sterility performed in the validation of a sterilization process
- ISO 11138-1:2017 Sterilization of health care products--Biological indicators--Part1: General Requirements
- ISO 11138-2:2017 Sterilization of health care products--Biological indicators--Part2: Biological indicators for ethylene oxide sterilization processes

Biocompatibility Testing:

- ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

- ISO 10993-4:2017: 2017 Biological Evaluation of Medical Devices, Part 4: Selection of test for interactions with blood.
- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical device--Part: 7: Ethylene Oxide sterilization residual.
- ISO 10993-10:2010 - Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Shelf Life Testing:

- ASTM F1886/F1886M -Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Performance Testing

The subject device is composed of biocompatible materials, has passed dielectric testing, and performs identical to the predicate devices. Bench tests used ex vivo tissue that included liver, kidney, and muscle tissue. The subject devices were tested to demonstrate the thermal effect on tissue by measuring the width and depth of the thermally damaged zones in relation to tissue type, intensity setting, and duration of activation. The temperature profile of the subject device applicator and cable was recorded during simulation use for the maximum energy delivery duration at the maximum power to demonstrate the maximum applicator surface area and maximum cable surface temperature will be safe to the user and/or to the patient. The peak temperatures of the electrode tips and target tissue/vessels when the device is used for the maximum recommended duration and generator output settings was compared. Based on the results of the various bench tests, it was determined that the subject device is safe and effective.

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 Bipolar Wands do not raise any issues of safety or effectiveness and are substantially equivalent to the predicate devices as described above.