November 2, 2020

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

Re: K202562
Trade/Device Name: Ellusa Generator and Monopolar Tips

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202562

Device Name
Ellusa Generator and Monopolar Tips

Indications for Use *(Describe)*
The Ellusa Generator is intended to provide high frequency energy for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels during surgical procedures and is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

The Ellusa Monopolar Tips are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures.

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))

(K202562)

October 28, 2020

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

Company Name and Address:
Ellusa, LLC
2473 Grand Avenue
Baldwin, NY 11510
Phone: (516) 866-0001
www.ellusa.com

Establishment Registration 3016087306

Contact Information:

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

Device Information (807.92(a)(2))

Trade Name: Ellusa Generator and Monopolar Tips

Common/Usual Name

Electrosurgical unit and accessories, electrosurgical cutting and coagulation device and accessories

Classification Name and Regulation

Electrosurgical Cutting and Coagulation Device and Accessories; 21 CFR 878.4400

Classification Panel

General and Plastic Surgery Device

Device Class/Product Code

FDA Classification: Class II
FDA Product Code: GEI

Predicate Device (807.92(a)(3))

Soniquence RF Generator & Monopolar Electrodes (K183611)

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 Generators are radiofrequency (RF) electrosurgical generators. It is a compact source of high-frequency RF energy employed for cutting and coagulation of soft tissue in a variety of surgical procedures. This action is achieved by front panel selection of waveforms and power levels. The subject device is designed to enable the performance of monopolar and bipolar functions for cutting, coagulation, and hemostasis in conjunction with separately-marketed electrosurgical accessories and ancillary equipment which have been developed for mutually- exclusive use with the Ellusa line of generators.

All selections are effected through push buttons and lamps, which give the operator feedback of status. The power level for each mode is indicated by front panel digital displays which also show the status of self-test and monitoring. The display is interlocked with controls to prevent operation when FAIL is displayed. The final output power control is made through foot and /or hand switches.

Ellusa Electrodes are used with the Ellusa Generator. The electrical power operating at radio frequency (RF) is transferred to tissue at the surgical site. The time-varying voltage produced by RF electrical power source yields a predetermined electrosurgical effect, such as tissue cutting or coagulation. The Ellusa family of electrodes is available in various shapes and sizes depending on the need of the surgeon. The devices are available in classic alloys (Tungsten, brass, stainless steel).

These devices are designed to comply with international safety standards including applicable IEC series electrical safety standards.

Intended Use:

The Ellusa Generator is intended to provide high frequency energy for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels during surgical procedures and is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

The Ellusa Monopolar Tips are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures.

Comparison of Technological Characteristics

The subject devices are substantially equivalent to the predicate devices 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 to the predicate devices.

Comparison of Generator models

Characteristic	Soniquence Generator K183611 PREDICATE	Ellusa Generator Type 1 Proposed Device	Ellusa Generator Type 2 Proposed Device	Ellusa Generator Type 3 Proposed Device
Photo				
Model numbers available	(Type 1 models) IEC6-SESP120, IEC6-IESP170, IEC6-IENSP170, IEC6-SESP170, IEC6-SENSP170 (Type 2 models) IEC6-IESU120, IEC6-IENSU120, IEC6-SENSU120, IEC6-SESU120, IEC6-IESU170, IEC6-IENSU170, IEC6-SESU170, IEC6-SENSU170 (Type 3 models) IEC6-IESV120, IEC4-SEN120, IEC6-SENSV120, IEC6-SESV120, IEC6-IESV170, IEC6-IENSV170, IEC6-SESV170, IEC6-SENSV170	IEC6-SEEP120 IEC6-IEEP170 IEC6-IENEP170 IEC6-SEEP170 IEC6-SENEP170 IEC4-ESM120 IEC4-ESP IEC3A-ES30W	IEC6-IEEU120 IEC6-IENEU120 IEC6-SENEU120 IEC6-SEEU120 IEC6-IEEU170 IEC6-IENEU170 IEC6-SEEU170 IEC6-SENEU170	IEC6-IEEV120 IEC4-SEN120 IEC6-SENEV120 IEC6-SEEV120 IEC6-IEEV170 IEC6-IENEV170 IEC6-SEEV170 IEC6-SENEV170 IEC4-EJSM120
Principle of Operation	Conversion of electrical energy to high-frequency RF energy (monopolar and bipolar)	Identical to predicate	Identical to predicate	Identical to predicate

Characteristic	Soniquence Generator K183611 PREDICATE		Ellusa Generator Type 1 Proposed Device	Ellusa Generator Type 2 Proposed Device	Ellusa Generator Type 3 Proposed Device
Modes of operation / mechanism of action	Cut	4.0 MHz square wave envelope 150W max. output	All Identical to predicate except models IEC4-ESM120, IEC4-ESP, & IEC3A-ES30W are max 120W output	Identical to predicate	All Identical to predicate except model IEC4-EJSM120 is max 120W output
	Blend	4.0 MHz square wave envelope 110W max. output	All Identical to predicate except models IEC4-ESM120, IEC4-ESP, & IEC3A-ES30W are max 90W output and the mode is called Cut/Coag	Identical to predicate	All Identical to predicate except model IEC4-EJSM120 is 90W output and the mode is called Cut/Coag.
	Hemo	4.0 MHz square wave envelope 60W max. output	Identical to predicate	Identical to predicate	Identical to predicate
	Bipolar	1.7 MHz CW sinusoidal wave 40W max output	Identical to predicate except models IEC4-ESM120, IEC4-ESP, & IEC3A-ES30W mode is called Bipolar Hemo (minor change in nomenclature only, function and performance stay the same)	Identical to predicate	All Identical to predicate except model IEC4-EJSM120 is Fulgurate (Monopolar) and 4.0 MHz Sinusoidal wave 40W max. output
	Bipolar Turbo	1.7 MHz square wave envelope 170W max. output	All Identical to predicate except models IEC4-ESM120, IEC4-ESP, & IEC3A-ES30W are max 120W output	Identical to predicate	All Identical to predicate except model IEC4-EJSM120 is max120W output and mode is Bipolar
Output frequency	4 MHz (monopolar) 1.7 MHz (bipolar)		Identical to predicate	Identical to predicate	Identical to predicate
Maximum power output	170W		All Identical to predicate except models IEC4-ESM120, IEC4-ESP, &	Identical to predicate	All Identical to predicate except model IEC4-EJSM120 is 120W

Characteristic	Soniquence Generator K183611 PREDICATE	Ellusa Generator Type 1 Proposed Device	Ellusa Generator Type 2 Proposed Device	Ellusa Generator Type 3 Proposed Device
		IEC3A-ES30W are 120W		
Voltage (peak-to-peak)	1,200V	Identical to predicate	Identical to predicate	Identical to predicate
Power activation control	Footswitch and/or fingerswitch	Identical to predicate	Identical to predicate	Identical to predicate
Electrical safety and EMC testing standards	AAMI ANSI ES60601-1 IEC 60601-1-2 IEC 60601-2-2	Identical to predicate	Identical to predicate	Identical to predicate
Applied part type	CF	All Identical to predicate except models IEC4-ESM120, IEC4-ESP, & IEC3A-ES30W are type BF	Identical to predicate	All Identical to predicate except model IEC4-EJSM120 is type BF

Comparison of Monopolar Tips

Predicate Information	Soniquence Monopolar Electrodes (K183611) PREDICATE	Ellusa Monopolar Tips PROPOSED DEVICE
Intended Use	The Soniquence Monopolar Electrodes are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures.	The Ellusa Monopolar Tips are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures.
Product Code	GEI	Identical to predicate
Device Classification	Class II	Identical to predicate
Functions	Cutting/coagulation	Identical to predicate
Energy type/ operating principle	Monopolar	Identical to predicate
Design Specifications	Integrated sterile components; handle, cable, connector, shaft, monopolar electrode	Identical to predicate
Shaft forms	Straight, Bayonet, angled, and curved	Identical to predicate
Shaft malleability	Fixed and malleable models	Identical to predicate
Shaft lengths	1.9 – 60 cm	Identical to predicate
Shaft diameter	1/16”	Identical to predicate
Tip Configurations	Loop (round, diamond), ball, and blade (needle, fine wired, spatula)	Identical to predicate

Material Composition Handle Shaft Electrode	 Molded Plastic Surgical Stainless Steel/Brass Surgical Stainless Steel/ Tungsten/Brass Surgical stainless steel / PFA insulation	Identical to predicate
Patient contacting materials	Medical grade stainless steel, brass, tungsten, Loctite, PFA, and PTFE	Identical to predicate
Coating	None	Identical to predicate
Biocompatibility	ISO 10993	Identical to predicate
Sterilization Methods	Gamma or Ethylene Oxide	Identical to predicate
Expiration Dating	Yes	Identical to predicate
Packaging	Sterile, Blister Tray Sterile, Peel Pouch	Identical to predicate
Activation Method	Fingerswitch/Footswitch	Identical to predicate
Manual Controls	No, all power settings established on generator	Identical to predicate
Min., Max., Default output Values (Wattage)	0-170	Identical to predicate
Cable Length (m)	3	Identical to predicate
Temperature Probe	No	Identical to predicate
Cooling Function	None	Identical to predicate

Summary of Technological Characteristics

The Ellusa Generator and Monopolar Tips are equivalent in intended use, technological characteristics, operating principle, and technical specifications to the predicate device Soniquence Generator and Monopolar Electrodes (K183611).

The differences of minor changes in nomenclature of operating modes does not affect the function or performance of the devices. In addition, the reduced output power on some models does not introduce new risks or affect the safety and effectiveness of the devices.

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

The Ellusa Generator and Monopolar Tips 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 in order to address identified risks and ensure the safety and effectiveness of the device. The following tests were successfully performed:

- AAMI ANSI ES60601-1 - Medical Electrical Equipment, Part l: General requirements for basic safety and essential performance

- IEC 60601-1-2 - Medical Electrical Equipment, Part l-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility
- IEC 60601-2-2 - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 62366 - Medical devices – Application of usability engineering to medical devices.

Sterilization of Monopolar Tips:

- ISO 11135 - 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 - Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ISO 11737-2 - Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process /
- ISO 11138-1 - Sterilization of health care products - Biological indicators - Part 1: General requirements

Biocompatibility Testing:

- ISO 10993-1 - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7 - Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals
- ISO 10993-10 - Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Shelf Life Testing:

- ASTM F1980-07 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Performance Testing:

- Software verification and validation in accordance with IEC 62304 and the FDA Final Guidance document titled “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”
- Energy output verification of each of the five modes and comparison to predicate.

- Thermal effect comparison for representative modes of the subject device and predicate on ex-vivo bovine tissue.
- A design verification /validation was conducted to validate the design and functionality of the generator and Monopolar Tip accessories. Tests included output power test, Hipot test, pull test, lateral heat spread in tissue test, evaluation of temperature profile, and final test. All tests passed their applicable acceptance criteria.

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 Ellusa Generator and Monopolar Tips are substantially equivalent to and as safe and effective as the predicate devices described above. The only difference between the subject devices of this 510k and the predicate devices is a rebranding with the Ellusa name. The technology remains the same.