May 22, 2019

Soniquence, LLC
Suzanne Lucas
Regulatory Affairs
2473 Grand Avenue
Baldwin, New York 11510

Re: K183611
Trade/Device Name: Soniquence RF Generator and Soniquence Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 22, 2019
Received: March 25, 2019

Dear Suzanne 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Jennifer R. Stevenson
Acting Division 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)*
K183611

Device Name
Soniquence RF Generator and Soniquence Electrodes

Indications for Use *(Describe)*
The Soniquence RF 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 Soniquence Electrodes 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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Exhibit 4. 510(k) SUMMARY

(As required by 21 CFR 807.92(a))

Date Prepared

May 22, 2019

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

Company Name and Address:

Soniquence, LLC
2473 Grand Avenue
Baldwin, NY 11510
Phone: (516) 654-4000
www.soniquence.com

Establishment Registration for Soniquence, LLC will be completed once this 510(k) has been FDA cleared.

Contact Information:

Suzanne Lucas – Regulatory Affairs
Phone: (516) 654-8017
Fax: (516) 654-8000
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Paul D. Buhrke IV– QA/RA Manager
Phone: (516) 277-9010
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Device Information (807.92(a)(2))
Trade Name: Soniquence RF Generator and Soniquence Electrodes

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 Devices (807.92(a)(3))

- Surgi-Max® Ultra (K170107)
- Bovie® IDS-310 Electrosurgical Generator (K134054)
- Elliquence Electrodes (K142410)
- Cobbra RF™ Tissue Dissector (K160041)

Device Description (807.92(a)(4))

The Soniquence RF 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 Soniquence® 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.

Soniquence Electrodes are used with the Soniquence RF 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

Soniquence 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 **Soniquence RF 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 **Soniquence Electrodes** are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures

Substantial Equivalence Comparison (807.92(a)(6))

The Soniquence RF Generator is substantially equivalent in both intended use and technological characteristics to the Surgi-Max® Ultra (K170107), as well as the Bovie® IDS-310 Electrosurgical Generator (K134054). An extensive comparison chart concerning key characteristics is provided on the following pages (Table 1.1).

Table 1.1 Substantial Equivalence Comparison Chart (RF Generator)

Predicate information	Soniquence RF Generator PROPOSED DEVICE	Surgi-Max® Ultra (K170107) PREDICATE	Bovie® IDS-310 Electrosurgical Generator (K134054) PREDICATE
Manufacturer	Soniquence, LLC	elliquence, LLC	Bovie Medical Corp.
Product code	GEI	GEI	GEI
Regulation number	Identical to predicates	21 CFR 878.4400	21 CFR 878.4400
Regulation name	Identical to predicates	Electrosurgical Cutting and Coagulation Device and accessories	Electrosurgical Cutting and Coagulation Device and accessories
Indications for use	The **Soniquence RF 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	**Orthopedic, arthroscopic, spinal, and neurological** For resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurological procedures. For soft tissue resection and ablation during arthroscopic surgical procedures of knee,	The IDS-310 High Frequency Electrosurgical Generator is used to deliver RF energy via an assortment of surgical devices to cut and coagulate different kinds of tissue.

	coagulate different kinds of tissue.	shoulder, ankle, elbow, hip and wrist. **Cutting** Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, Blepharoplasty. **Blended Cutting and Coagulation** Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, skin tags, papilloma Keloids, Keratosis, Verrucae, Basal Cell Carcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of skin flaps. **Hemostasis and Nonablative Coagulation** Control of bleeding, Epilation, Telangiectasia **Bipolar** Pinpoint, Precise Coagulation, Pinpoint Hemostasis, in any field (wet or dry), snoring, sub•mucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage.	
Prescription device (21 CFR 801.109)	Identical to predicates	Yes	Yes

Principle of Operation	Identical to predicates	Conversion of electrical energy to high-frequency RF energy (monopolar and bipolar)	Conversion of electrical energy to high-frequency RF energy (monopolar and bipolar)
Modes of operation	Identical to elliquence K170107	Cut Blend Hemo Bipolar Bipolar Turbo	9 Monopolar and 4 bipolar modes
Output frequency	Identical to elliquence K170107	4 MHz (monopolar) 1.7 MHz (bipolar)	350 – 490 kHz (monopolar) 490 kHz (bipolar)
Maximum power output	Identical to elliquence K170107	170W	300W
Voltage (peak-to-peak)	Identical to elliquence K170107	1,200V	8,000V
Duty Cycle	Identical to elliquence K170107	10 sec On / 30 sec OFF	10 sec On / 30 sec OFF
Supply input power	Identical to elliquence K170107	100 VAC – 240 VAC, 50/60 Hz	100 VAC – 240 VAC, 50/60 Hz
Power activation control	Identical to predicates	Footswitch and/or fingerswitch	Footswitch and/or fingerswitch
Electrical safety and EMC testing standards	Identical to elliquence K170107	AAMI ANSI ES60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2
Applied part type	Identical to elliquence K170107	CF	CF

Table 1.2 – Substantial equivalence comparison table (Electrodes)

Predicate Information	**Soniquence Electrodes** **PROPOSED DEVICE**	**Elliquence Electrodes** **(K142410)** **PREDICATE**	**Cobbra™ RF Tissue Dissector (K160041)** **PREDICATE**
Intended Use	The **Soniquence Electrodes** are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures.	The Elliquence Electrodes are intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures. The types	Intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures. General surgery, laparoscopic, procedures, endoscopic procedures, open

		of surgery intended are: General surgery, Laparaoscopic procedures, Endoscopic procedures, Open abdominal, Orthopedic coagulation, Thorascopic coagulation, Neurosurgical coagulation, Gynecological coagulation, (except for use in female sterilization), Ear, Nose, Throat coagulation.	abdominal, orthopedic coagulation, thorascopic coagulation, neurosurgical coagulation, gynecological coagulation, and ENT coagulation are the types of intended surgeries.
Product Code	Identical to predicates	GEI	GEI
Device Classification	Identical to predicates	Class II	Class II
Functions	Identical to predicates	Cutting/coagulation	Cutting/coagulation
Energy type/ operating principle	Identical to predicates	Monopolar	Monopolar
Design Specifications	Identical to predicates	Integrated sterile components; handle, cable, connector, shaft, monopolar electrode	Integrated sterile components; handle, cable, connector, shaft, monopolar electrode
Shaft forms	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	Straight, Bayonet, angled, and curved	Straight
Shaft malleability	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	Fixed and malleable models	Fixed models only
Shaft lengths	Identical to predicate	1.9 – 60 cm	electrode shaft: 12.7 cm handpiece shaft: 18.55 cm
Shaft diameter	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	1/16” and 3/32”	electrode shaft: 6.0 mm handpiece shaft: 21.7 mm

Tip Configurations	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	Loop (round, diamond), ball, and blade (needle, fine wired, spatula)	Spatula
Material Composition Handle Shaft Electrode	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	Molded Plastic Surgical Stainless Steel/Brass Surgical Stainless Steel/ Tungsten/Brass	Molded plastic Surgical stainless steel Surgical stainless steel / PFA insulation
Patient contacting materials	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	Medical grade stainless steel, brass, tungsten, Loctite, PFA, and PTFE	Medical grade stainless steel and PFA
Coating	Identical to predicates	None	None
Biocompatibility	Identical to predicates	ISO 10993	ISO 10993
Sterilization Methods	Identical to predicates	Gamma or Ethylene Oxide	Gamma or Ethylene Oxide
Expiration Dating	Identical to predicates	Yes	Yes
Packaging	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	Sterile, Blister Tray Sterile, Peel Pouch	Sterile, Blister Tray
Activation Method	Identical to predicates	Fingerswitch/Footswitch	Fingerswitch/Footswitch
Manual Controls	Identical to predicates	None, all power settings established on generator	None, all power settings established on generator
Internal Memory/ circuitry for generator recognition	Identical to predicates	None	None

Min., Max., Default output Values (Wattage)	Identical to predicates	0-170	0-170
Patient Leakage current	Identical to predicates	Type CF	Type CF
Cable Length (m)	Cobbra models identical to Cobbra predicate All others are identical to Elliquence Electrodes predicate	3	3
Temperature Probe	Identical to predicates	No	No
Cooling Function	Identical to predicates	None	None

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

The Soniquence RF Generator and Soniquence Electrodes 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 I: General requirements for basic safety and essential performance
- IEC 60601-1-2 - Medical Electrical Equipment, Part I-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.
- 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 11737-2:2009 - 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
- 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
- ASTM F1980-07 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- 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.

Technological Characteristics

The devices are substantially equivalent to the predicate devices based on a comparison of physical and performance characteristics.

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, Soniquence, LLC concludes that the Soniquence RF Generator and Soniquence Electrodes are substantially equivalent to the predicate devices as described above.