



June 20, 2019

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

Re: K190336
Trade/Device Name: Soniquence Bipolar 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/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

Indications for Use

510(k) Number (if known)

K190336

Device Name

Soniquence Bipolar Electrodes

Indications for Use (Describe)

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.

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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K190336

Exhibit 4. 510(k) SUMMARY

(As required by 21 CFR 807.92(a))

Date Prepared

May 6, 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
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Device Information (807.92(a)(2))

Trade Name: Soniquence Bipolar Electrodes

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))

- Meddusa Bipolar System (K130110)
- Trigger Flex Electrodes (K003126)

Device Description (807.92(a)(4))

The Soniquence Bipolar Electrodes 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 Soniquence Bipolar Electrodes 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 Soniquence 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 Soniquence Bipolar Electrode emits RF energy generated according to settings established on the Soniquence RF 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 Soniquence Bipolar Electrode is intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed.

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

The Soniquence Bipolar Electrodes are substantially equivalent in intended use and identical in technological characteristics to the Meddusa Bipolar System (K130110), and the Bipolar Trigger-Flex Electrode (K003126). An extensive comparison chart concerning key characteristics is provided in the Substantial Equivalence section.

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

The Soniquence Bipolar 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:

• IEC 60601-1:2005/(R)2012 and A1:2012 - Medical Electrical Equipment, Part I: 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 I-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility
• IEC 60601-2-2: 2009 +A11:2011 - 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
• 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 11737-1:2006 Sterilization of medical products--Microbiological methods--Part 1: Determination of population of microorganisms on product
• ISO 11737-2:2009 Sterilization of medical devices--Microbiological methods--Part 2: Tests of sterility performed in the validation of a sterilization process
• ISO 11138-1:2006 Sterilization of health care products--Biological indicators--Part1: General Requirements
• ISO 11138-2:2006 Sterilization of health care products--Biological indicators--Part2: Biological indicators for ethylene oxide sterilization processes
• ISO 10993-7:2008 Biological evaluation of medical device--Part: 7: Ethylene Oxide sterilization residual.
• ISO 10993-4:2002+Amd 1 :2006: Biological Evaluation of Medical Devices, Part 4: Selection of test for interactions with blood.
• 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 10993-10 - 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 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 Data

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.

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, Sonique, LLC concludes that the subject device, Sonique Bipolar Electrodes does not raise any issues of safety or effectiveness and are substantially equivalent to the predicate devices as described above.