September 2, 2022

Soniquence, LLC
Ms. Suzanne Lucas, B.A
Sr. Regulatory Affairs Specialist
2477 Grand Avenue
Baldwin, New York 11510

Re: K212222
Trade/Device Name: Soniquence Reusable 3 Button Fingerswitch Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 3, 2022
Received: August 8, 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)*
K212222

Device Name
Soniquence Reusable 3 Button Fingerswitch Wand

Indications for Use *(Describe)*
The Soniquence Reusable 3 Button Fingerswitch Wand is designed to be used with a Soniquence RF Generator and Soniquence monopolar electrodes for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exhibit 2. 510(k) SUMMARY

(As required by 21 CFR 807.92(a))

Date Prepared

August 30, 2022

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

Company Name and Address:

Soniquence, LLC
2477 Grand Avenue
Baldwin, NY 11510
Phone: (516) 634-1370
www.soniquence.com

Establishment Registration #: 3014982808

Contact Information:

Ms. Suzanne Lucas
Soniquence, LLC
Sr. Regulatory Affairs Specialist
Phone: (516) 634-1370
Email: slucas@soniquence.com

Device Information (807.92(a)(2))

Trade Name: Soniquence Reusable 3 Button Fingerswitch Wand

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))

- Soniquence Disposable 3 Button Fingerswitch Handpiece (K183611)

Device Description (807.92(a)(4))

The subject device Soniquence Reusable 3 Button Fingerswitch Wand is an accessory to the Soniquence SmoothWave RF Generator. It is connected to a High Frequency Generator via the male end, and the female end termination connects to the Monopolar Electrode. This device will be provided non-sterile and is intended to be used with Soniquence Monopolar Electrodes.

The 3-Button Fingerswitch Wand includes access to all three monopolar waveforms without unit manipulation. This patented, unique handpiece is utilized to activate CUT, BLEND, and HEMO modes via fingerswitch for general surgical procedures. The depressed button function will be the actual output function and disregards the front display settings. The fingerswitch operational features are as follows:

a) The CUT button will activate CUT mode. When depressed, the yellow indicator (CUT) illuminates.
b) The BLEND button will activate BLEND mode. When depressed, the yellow indicator (BLEND) illuminates.
c) The HEMO button will activate the HEMO mode. When depressed, the blue indicator (HEMO) illuminates.

Intended Use:

The Soniquence Reusable 3 Button Fingerswitch Wand is designed to be used with a Soniquence RF Generator and Soniquence monopolar electrodes for resection, dissection, incision, and hemostasis in soft tissue surgical procedures.

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

The Soniquence Reusable 3 Button Fingerswitch Wand is substantially equivalent in intended use, technological characteristics, operating principle, and performance characteristics to the predicate device.

Characteristic	Soniquence Reusable 3 Button Fingerswitch Wand (SUBJECT DEVICE)	Soniquence 3 Button Fingerswitch Wand (K183611) PREDICATE
Intended Use	The Soniquence Reusable 3 Button Fingerswitch Wand is designed to be used with a Soniquence RF Generator and Soniquence monopolar electrodes for resection, dissection, incision, and hemostasis in soft tissue surgical procedures.	The Soniquence 3 Button Fingerswitch Wand is designed to be used with a Soniquence RF Generator and Soniquence monopolar electrodes for resection, dissection, incision, and hemostasis in soft tissue surgical procedures.
Regulation number	21 CFR 878.440	21 CFR 878.440
Product Code	GEI	GEI
OTC or Prescription	RX Only	RX Only
Device Classification	Class II	Class II
General description of procedures	Soft tissue surgical procedures	Soft tissue surgical procedures
Modes of operation	Monopolar Cut, Blend, and Hemo	Monopolar Cut, Blend, and Hemo
Operating mechanism	Button Switch	Button Switch
Energy Type	Radio Frequency	Radio Frequency
Electrode Tip configurations	Ball, Loop, Wire, Needle, Spatula, Diamond	Ball, Loop, Wire, Needle, Spatula, Diamond
Shaft working length	20mm – 180mm	20mm – 180mm
Activation Method	Hand control	Hand control
Materials	ABS, TPE	ABS, TPE

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

The Soniquence Reusable 3 Button Fingerswitch Wand 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.

Electrical Safety -The following tests were successfully performed:

- IEC 60601-1: 3rd edition, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- 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

Biocompatibility:
The device was subjected to the following biocompatibility tests which passed all tests.

- Intracutaneous Reactivity Test, ISO 10993-10:2010, Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
- Skin Sensitization Test, ISO 10993-10:2010, Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
- In Vitro Cytotoxicity, ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Sterilization Validation: The device has undergone sterilization validation reprocessing with passing results according to the requirements of:

- ISO 14937:2009 - Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices
- AAMI TIR12:2020 – Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ASTM E1766-15 - Standard Test Method for Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices

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 subject device, Soniquence Reusable 3 Button Fingerswitch Wands does not raise any issues of safety or effectiveness and are substantially equivalent to the predicate device as described above.