January 27, 2026

Soniquence, LLC
Suzanne Lucas
QA/RA Manager
2477 Grand Ave.
Baldwin, New York 11510

Re: K254220
Trade/Device Name: 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: December 22, 2025
Received: December 29, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.01.27 10:20:55 -05'00'

Colin Kejing Chen, Ph.D.
Acting 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254220

Please provide the device trade name(s).

Reusable 3 Button Fingerswitch Wand

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY K254220

(As required by 21 CFR 807.92(a))

Date Prepared

December 23, 2025

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:

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QA/RA Manager
Soniquence, LLC
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Device Information (807.92(a)(2))

Trade Name: Soniquence 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 3 Button Fingerswitch Handpiece, disposable (K183611)
- Soniquence 3 Button Fingerswitch Handpiece, reusable (K212222)

Device Description (807.92(a)(4))

The Soniquence 3-Button Fingerswitch Wand is an accessory intended for use with the Soniquence SmoothWave RF Generator. The device connects to a high-frequency generator via a male connector, and the distal female connector interfaces with a compatible Soniquence monopolar electrode. The device is supplied non-sterile and is intended for use with Soniquence monopolar electrodes.

The 3-Button Fingerswitch Wand provides user access to three monopolar waveforms without the need for generator front-panel manipulation. The handpiece enables activation of CUT, BLEND, and HEMO modes via integrated finger-actuated switches. When a button is depressed, the corresponding mode is activated regardless of the generator display settings. Visual indicators illuminate to confirm activation of the selected mode.

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

Subject Device 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

Predicate Device Intended Use (K183611) Disposable 3 Button Fingerswitch Wand

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

Predicate Device Intended Use (K212222) Reusable 3 Button Fingerswitch Wand

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 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 disposable 3 Button Fingerswitch Wand (PREDICATE DEVICE K183611)	Soniquence reusable 3 Button Fingerswitch Wand (PREDICATE DEVICE K212222)
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 exclusively with a Soniquence RF Generator and the Soniquence monopolar electrodes for resection, dissection, incision and hemostasis in soft tissue surgical procedures.	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
Regulation number	878.4400	Identical	Identical to both
Product Code	GEI	Identical	Identical to both
OTC or Prescription	RX Only	Identical	Identical to both
Device Classification	Class II	Identical	Identical to both
Modes	Monopolar Cut, Blend, and HEMO modes	Identical	Identical to both
Operating mechanism	Button Switch	Identical	Identical to both
Energy Source	RF Energy	Identical	Identical to both
Cable length (m)	3m	Identical	Identical to both
Activation method	Hand control	Identical	Identical to both
Materials	Housing: Aluminum Alloy	Housing: ABS	Identical to disposable 3 Button Fingerswitch Wand K183611
	Activation buttons: Silicone rubber compound	Activation buttons: ABS	Identical to disposable 3 Button Fingerswitch Wand K183611
	Button cover: Polyphenylsulfone	Button cover: ABS	Identical to disposable 3 Button Fingerswitch Wand K183611
	Internal electronics: Printed circuit board (PCB	Identical	Identical to both
	Cable insulation: Silicone	Cable insulation: PVC	Identical to disposable 3 Button Fingerswitch Wand K183611

Characteristic	Soniquence Reusable 3 Button Fingerswitch Wand (SUBJECT DEVICE)	Soniquence disposable 3 Button Fingerswitch Wand (PREDICATE DEVICE K183611)	Soniquence reusable 3 Button Fingerswitch Wand (PREDICATE DEVICE K212222)
Safety standards used	• IEC 60601-1 (Electrical safety) • IEC 60601-2-2 (HF surgical equipment)	Identical	Identical to both
Biocompatibility	• ISO 10993-11: 2017 Acute systemic toxicity • ISO 10993-10:2021 Skin Sensitization • ISO 10993-23:2021 Intracutaneous irritation • USP-NF General Chapters 151 – Pyrogen test • ISO 10993-5:2009 MTT Cytotoxicity	Identical	Identical to both
Sterility method	Pre-Vacuum Sterilization	EO Sterilization	Steris V-Pro Sterilization

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

The Soniquence 3-Button Fingerswitch Wand was developed in accordance with the design control requirements of 21 CFR 820.30. Appropriate non-clinical verification and validation testing was conducted to address identified risks and to support the safety and effectiveness of the device.

Testing included:

- IEC 60601-1: Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-2-2: Medical electrical equipment – Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and accessories

Biocompatibility
Biocompatibility testing was conducted in accordance with ISO 10993 for externally communicating devices with tissue contact. All tests met acceptance criteria.

- ISO 10993-10:2010, Intracutaneous Reactivity Test
- ISO 10993-10:2010, Skin Sensitization Test
- ISO 10993-5:2009, Cytotoxicity
- ISO 10993-11: 2017 Acute systemic toxicity
- USP-NF General Chapters 151 – Pyrogen test

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

- ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices
- ISO 17665:2024 Sterilization of health care products — Moist heat — Requirements for 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
- ANSI/AAMI ST98:2022 Cleaning validation of health care products — Requirements for development and validation of a cleaning process for medical devices
- ASTM F3208-20 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

Clinical Testing (807.92(b)(2))
Clinical testing was not required to demonstrate substantial equivalence.

Conclusion (807.92(b)(3))
Based on the comparison of intended use, technological characteristics, and performance to the identified predicate devices, Soniquence, LLC concludes that the Soniquence 3 Button Fingerswitch Wand does not raise new or different questions of safety or effectiveness and is substantially equivalent to the predicate devices.