November 5, 2021

Soliton Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K212502
Trade/Device Name: Resonic Rapid Acoustic Pulse Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 9, 2021
Received: August 9, 2021

Dear Janice Hogan:

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,

Purva Pandya
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)*

K212502

Device Name

Resonic™ Rapid Acoustic Pulse device

Indications for Use *(Describe)*

The Soliton Resonic™ Rapid Acoustic Pulse device is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The Resonic device is also indicated for long-term improvement in the appearance of cellulite as supported by clinical data demonstrating treatment benefits up to 1 year of observation.

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

Soliton Resonic™ Rapid Acoustic Pulse Device

K212502

Submitted by: Soliton, Inc.
5304 Ashbrook Drive
Houston, TX 77081

Contact Person: Leslie Honda
VP, Regulatory Affairs and Quality Systems
Tel: 206.375.8586

Date Prepared: October 28, 2021

Trade Name: Soliton Resonic™ Rapid Acoustic Pulse Device

Common Name: Dermatology Laser System

Classification: Class II
Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product Code GEX

Predicate Device: Soliton Resonic™ Rapid Acoustic Pulse Device (K210964)

Indications for Use:

The Soliton Resonic™ Rapid Acoustic Pulse device is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The Resonic device is also indicated for long-term improvement in the appearance of cellulite as supported by clinical data demonstrating treatment benefits up to 1 year of observation.

Device Description:

The Soliton Resonic™ Rapid Acoustic Pulse device is designed as an accessory to laser treatments to improve laser tattoo fading efficiency, as well as a standalone device to improve the appearance of cellulite. Resonic uses repeated, rapidly rising acoustic waves, releasing pigment particles from the pigment laden macrophage (PLM) and dissipating the laser-induced whitening. This allows multiple laser passes in a single session, resulting in accelerated tattoo fading and fewer office visits to achieve sufficient tattoo fading. When used for improving the appearance of cellulite, the acoustic waves induce physical effects in the fibrous structures, such as the fibrous septa in the subcutaneous tissue.

Summary of Technological Characteristics:

The Soliton Resonic™ Rapid Acoustic Pulse device is composed of three parts: the Console, the Hand Piece and the Cable connecting the Hand Piece to the Console. The Console supplies saline to the Hand Piece to enable formation of the shock wave within the acoustic pulse chamber. The Hand Piece generates acoustic waves in the saline. The acoustic waves

pass through the acoustically transparent window and acoustic ultrasound gel or similar hydrogel pad, which when placed against the surface of the skin to be treated.

The subject RAP device is almost identical to the previously cleared Resonic device. The primary purpose of this submission is to update the indications for use to reflect the long-term clinical data through one year. With respect to the technology, only minor changes have been made. These changes do not alter the scientific technology or the use of the modified device. Specifically, the shape, frequency and repetition rate of the acoustic waves are not changed.

Substantial Equivalence Comparison Table

	Soliton Resonic™ Rapid Acoustic Pulse Device (K212502; Subject Device)	**Soliton Resonic™ Rapid Acoustic Pulse Device (K210964; Predicate Device)**	**Comparison**
Indications for Use	The Soliton Resonic™ Rapid Acoustic Pulse device is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The Resonic device is also indicated for long-term improvement in the appearance of cellulite as supported by clinical data demonstrating treatment benefits up to 1 year of observation.	The Soliton Resonic™ Rapid Acoustic Pulse device is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The Resonic device is also indicated for short-term improvement in the appearance of cellulite.	Indications for use updated based on long-term follow-up data.
Device Technology	Tattoo treatment mode: Acoustic waves to dissipate the opaque “whitening” caused by the microbubbles formed after exposure to Q-switched laser. Cellulite treatment mode: External electrodes to rapidly heat water which produces an acoustic pulse that partially disrupts the fibrous septa to improve cellulite appearance.	Tattoo treatment mode: Acoustic waves to dissipate the opaque “whitening” caused by the microbubbles formed after exposure to Q-switched laser. Cellulite treatment mode: External electrodes to rapidly heat water which produces an acoustic pulse that partially disrupts the fibrous septa to improve cellulite appearance.	Same
Acoustic Wave Type	Acoustic shock wave	Acoustic shock wave	Same

Acoustic Wave Frequency	Broadband/Ultrasonic	Broadband/Ultrasonic	Same
Repetition rate	Tattoo treatment mode: 100 Hz Cellulite treatment mode: 50 Hz	Tattoo treatment mode: 100 Hz Cellulite treatment mode: 50 Hz	Same
Waveform	Pulsed	Pulsed	Same
Spot Size	38 mm	38 mm	Same
Peak Fluence	0.0029 J/cm^2	0.0029 J/cm^2	Same
Peak Acoustic Pressure	0.25 to 12 MPa	0.25 to 12 MPa	Same
Primary Components	Console Energy Conduit (Cable) Hand piece	Console Energy Conduit (Cable) Hand piece	Same
Hand Piece Components	Hand Piece Grip Cartridge	Hand Piece Grip Cartridge	Same
Electrical Safety/EMC	IEC 60601-1 Compliant IEC 60601-1-2 Compliant	IEC 60601-1 Compliant IEC 60601-1-2 Compliant	Same
Input Power	240VAC 60Hz	240VAC 60Hz	Same
Fuse Rating	15 A	15 A	Same
User Interface	LCD Touch Screen Graphic User Interface	LCD Touch Screen Graphic User Interface	Same
System Dimensions	56” x 17.7” x 13.8”	56” x 17.7” x 13.8”	Same
Weight	220 lbs.	220 lbs.	Same
Foot Switch Activation	Yes	Yes	Same
Single Use Disposable Component	Cartridge	Cartridge	Same

Performance Data:

Electrical safety and electromagnetic compatibility (EMC) testing was performed for the Resonic RAP device by an independent test laboratory in accordance with IEC 60601-1,

Medical electrical equipment, Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

The biocompatibility of the Resonic RAP device is established based on the evaluation of the previous version of the device as there is no change to the patient contacting components.

Software verification testing was conducted and the testing results were found acceptable for software release.

All performance testing demonstrated that Resonic RAP performs according to specifications and functions as intended.

Clinical Study Data:

The Resonic RAP device was evaluated in a single arm, self-controlled, prospective, multi-site trial to assess the safety and effectiveness of the device for its indicated use for the improvement in the appearance of cellulite. A total of 67 participants were enrolled at 4 sites in the United States and received one treatment session on the buttock and/or thigh areas. The mean age was 43 years and the majority of the participants were Caucasian.

All treatment sites were treated with multiple 1-minute doses of RAP to cover the site. Serial clinical photographs were collected under standardized conditions before treatment (baseline) and at the 12-week and 52-week follow-up visits. Photographs were assessed by blinded independent reviewers to identify pre-treatment images when compared to post treatment images. Patient satisfaction was assessed by participants' responses to the satisfaction survey. Safety assessments included evaluation of AEs via physician examination during and after the treatment.

The 12-week results were previously submitted in K201801 to support the indicated use of the device for the short-term improvement in the appearance of cellulite. The 52-week results are now provided to support the long-term improvement by demonstrating no significant reduction in treatment benefits up to 1 year of observation.

The primary effectiveness endpoint of the long-term study was met as the blinded physician panel correctly identified the long-term (>52-weeks) post-treatment photograph in 95.2% of the cases. The mean cellulite severity score reduction was 1.09. At 52 weeks, all participants found their treatment areas to appear improved compared to the pre-treatment photos, and 97.6% of participants found there was good improvement in the appearance of cellulite.

The safety of the Resonic RAP device was evaluated based on the adverse events reported during the study. All adverse events observed were categorized as mild or moderate and were expected. No adverse events were related to the device. There were no serious adverse events.

The study results demonstrated that the treatment effect with Resonic RAP device in improving the appearance of cellulite is maintained through 1 year after the treatment.

Conclusions:

Resonic RAP and its predicate device have the same intended use and similar indications for use, technological characteristics and principles of operation. The minor differences in the technological characteristics do not present different questions of safety or effectiveness as compared to the predicate device. Nonclinical testing of the device demonstrated that the device performs as intended. Clinical testing confirms that the treatment effect with the device in improving the appearance of cellulite is maintained through one year after the treatment. Therefore, Resonic RAP is substantially equivalent to the predicate device.