



April 27, 2021

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

Re: K210964

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: March 31, 2021

Received: March 31, 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

510(k) Number (if known)

K210964

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 short-term improvement in the appearance of cellulite.

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**

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: March 31, 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 Devices: Soliton Rapid Acoustic Pulse Device (K201801)

Intended 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 short-term improvement in the appearance of cellulite.

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 Resonic RAP is a modification to the company's Rapid Acoustic Pulse (RAP) device that has already been cleared for the same indications for use (K201801). Only minor hardware and software changes have been made. These changes do not alter the fundamental scientific technology of the modified device. Specifically, the shape, frequency and repetition rate of the acoustic waves are not changed.

Performance Data:

In accordance with Soliton's design control procedures, risk analysis was conducted to assess the impact of the modifications on the device. Verification testing using the same methods as

used for the predicate device demonstrates that the Resonic RAP device functions as specified and is as safe and effective as its predicate device.

Electrical safety and electromagnetic compatibility (EMC) testing was repeated 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 Resonic RAP device is established based on the evaluation of the RAP. No new materials are used on the surface of the device that contacts the patient skin.

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

Conclusions:

The Resonic RAP device is as safe and effective as the predicate RAP device previously cleared in K201801. The Resonic RAP device and its predicate device have the same intended use and indications for use, and similar technological characteristics and principles of operation. The minor differences in the newer device version (the subject device) do not alter the fundamental technological characteristics or present different questions of safety or effectiveness as compared to the predicate device. Thus, The Resonic RAP device is substantially equivalent to the predicate device.