Soliton Inc.
℅ Janice Hogan
Regulatory Counsel
Hogan Levells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

March 10, 2020

Re: K200331
Trade/Device Name: 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: February 10, 2020
Received: February 10, 2020

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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
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: June 30, 2020
See PRA Statement on last page

510(k) Number *(if known)*
K200331

Device Name

Rapid Acoustic Pulse Device

Indications for Use *(Describe)*

The Rapid Acoustic Pulse Device (RAP) 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.

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

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 9, 2020
Trade Name:	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 Acoustic Wave Device (K190542) (Predicate device)

Intended Use / Indications for Use:

The Rapid Acoustic Pulse Device (RAP) 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.

Summary of Technological Characteristics

The Soliton Rapid Acoustic Pulse Device (RAP) is designed as an accessory to laser treatments for tattoo removal. The RAP 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 fewer office visits.

The RAP is composed of three parts: the Console, the Hand Piece and the connecting Cable. 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 tattoo to be removed, penetrates the skin to the typical depth of tattoo ink.

The RAP is a modification to the company's Acoustic Wave Device (AWD) that has already been cleared for the same indications for use (K190542). 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 RAP functions as specified and is as safe and effective as its predicate device.

Electrical safety and electromagnetic compatibility (EMC) testing was repeated for the 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 RAP device is established based on the evaluation of the AWD. 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 RAP device is as safe and effective as the predicate AWD device previously cleared in K190542. RAP 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, RAP is substantially equivalent to the predicate device.