January 29, 2021

Soliton Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LPP
1735 Market Street
Suite 2300
Philadelphia, Pennsylvania 19103

Re: K201801
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: January 4, 2021
Received: January 4, 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
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

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)*

K201801

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. The RAP 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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K201801

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:	
Trade Name:	Rapid Acoustic Pulse Device
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:	Cynosure's Cellulaze Laser (K102541) (Primary predicate device) Soliton's Rapid Acoustic Pulse Device (K200331 (Reference device)

Device Description:

The Rapid Acoustic Pulse Device (RAP) 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. 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 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.

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. The RAP device is also indicated for short-term improvement in the appearance of cellulite.

Summary of Technological Characteristics:

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 skin to be treated.

The subject RAP device is almost identical to the previously cleared RAP device. The only hardware change to the device is the modified shape of the reflector that is part of the Hand Piece, so that the acoustic wave is less dispersed and penetrates deeper in the subcutaneous tissue where fibrous septa are located.

Performance Data

Electrical safety and electromagnetic compatibility (EMC) testing for RAP was conducted 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 is established based on the evaluation of the previous version of RAP 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 RAP performs according to specifications and functions as intended.

Clinical Study Data

The 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 temporary 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 primary analysis was conducted in 62 participants who completed a full treatment of the identified treatment areas and who completed the 12 week follow up visit. 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 follow-up visits. Photographs were assessed by blinded independent reviewers to identify pre-treatment images when compared to post treatment images and to grade the pre-treatment and post-treatment images using the CSS and improvement using the Global Aesthetic Improvement Scale (GAIS). Safety assessments included evaluation of AEs via physician examination during and after the treatment.

Most participants found RAP treatment to be tolerable, with average pain during the entire treatment session rated as 2.4 using a 0 to 10 numeric pain rating scale. In addition, participants were generally satisfied with the treatment and the results.

The safety of RAP was evaluated based on the adverse events reported during the study. All adverse events observed during the study were categorized as mild or moderate and were expected. All symptoms were transient and resolved without intervention. No adverse events were identified as serious or severe. No participants asked to stop the treatment or dropped out of the study due to any adverse event.

Based on the patient satisfaction and safety profile as documented in the pivotal clinical study, RAP was found to have a safety and effectiveness profile that is substantially equivalent to the predicate device.

Conclusions

RAP and its predicate devices have the same general intended use and similar indications for use, technological characteristics and principles of operation. Moreover, the differences in the technological characteristics do not present different questions of safety or effectiveness as compared to the predicate devices. Nonclinical and clinical testing of RAP demonstrated that the device performs as intended with a favorable safety profile. Clinical testing confirms that the differences in technology compared to the predicate do not adversely impact performance, in support of substantial equivalence. Therefore, RAP is substantially equivalent to the predicate devices.