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

May 24, 2019

Re: K190542
Trade/Device Name: Soliton Acoustic Wave 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: QHF
Dated: March 4, 2019
Received: March 4, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Jennifer Stevenson
Acting 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)*

K190542

Device Name

Soliton Acoustic Wave Device

Indications for Use *(Describe)*

The Soliton Acoustic Wave Device (AWD) is indicated for use as as an accessory to laser tattoo removal procedures using a 1064 nm Q-Switched laser 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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K190542

**510(k) SUMMARY**

**Soliton Acoustic Wave Device**

| | |
|---|---|
| **Submitted by:** | Soliton, Inc.<br>5304 Ashbrook Drive<br>Houston, TX 77081 |
| **Contact Person:** | Leslie Honda<br>VP, Regulatory Affairs and Quality Systems<br>Tel: 206.375.8586 |
| **Date Prepared:** | May 14, 2019 |
| **Trade Name:** | Soliton Acoustic Wave Device |
| **Common Name:** | Dermatology Laser System |
| **Classification:** | Class II<br>Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810) |
| **Predicate Device:** | ON Light Science's DeScribe® Transparent PFD Patch (K150212) |

**Device Description**

The Soliton Acoustic Wave Device (AWD) is designed as an accessory to laser treatments for tattoo removal. The AWD 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.

**Intended Use / Indications for Use:**

The Soliton Acoustic Wave Device (AWD) is indicated for use as an accessory to laser tattoo removal procedures using a 1064 nm Q-Switched laser in Fitzpatrick Skin Type I-III patients.

**Summary of Technological Characteristics**

The Soliton AWD 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 shape, frequency and repetition rate of these acoustic waves are optimized to diffuse gas bubbles (vacuoles) caused by the use of a Q-switched laser without damaging adjacent non-pigmented tissue. Removing them by using the Soliton AWD allows another Q-switched laser treatment to be performed immediately instead of waiting for the body to remove the gas pockets and heal over a period of 4-6 weeks between standard laser treatments.

**Performance Data**

Electrical safety and electromagnetic compatibility (EMC) testing for the AWD 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 the AWD is established by biocompatibility evaluations consistent with the guidelines in FDA's "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" Guidance Document.

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

All performance testing demonstrated that the AWD performs according to specifications and functions as intended.

**Animal Study Data**

The AWD was evaluated using Gottingen Mini-pigs tattooed with multiple circular black tattoo spots. Tattoo sites were treated with either a single-pass Q-switched Nd:YAG laser treatment (Laser Only), or multiple-pass laser treatment with each laser treatment followed by an AWD application (Laser+AWD). Dermal clearing was assessed histologically and colorimetrically using a handheld colorimeter. The dermal effects of using AWD as an accessory to the laser were assessed histologically both immediately and at 48-72 hours post treatment. Additionally, the treatment sites were assessed photographically at 10-12 weeks.

The results of this study demonstrate that when used as an accessory to a Q-switched Nd:YAG laser in the treatment of tattoos, AWD clears laser-induced dermal whitening. The use of Laser+AWD was also shown to be safe. After 10 to 12 weeks of healing the photographic appearance of the epidermis at the treatment sites was normal, showing no residual epidermal changes.

**Clinical Study Data**

The Soliton AWD was evaluated in a single-center, prospective study to assess the safety and efficacy of the device for its indicated use in tattoo removal. The clinical study enrolled 24 subjects with 35 tattoos at an investigational site in the U.S. The majority of subjects were female, Fitzpatrick Skin Type I-III, with a mean age of 34 years.

Each tattoo was divided into 3 approximately equal areas. Each end area was designated for treatment with either a single laser pass (Laser Only) or multiple consecutive laser passes alternating with AWD (Laser+AWD). The middle area of the tattoo between the treated areas served as the control and was not treated. Each subject was assessed at baseline, post-treatment, and during follow up after treatment. For the primary endpoint analysis, the number of laser treatment passes delivered in a single session was recorded.

In addition, the subjects' tattoos were evaluated by blinded independent evaluators, as well as the study investigator. Any potential safety effects were recorded.

The primary effectiveness endpoint of the study was met as the mean number of laser passes delivered in a single treatment session with AWD treatment was 4.16, with a lower limit of 95% confidence interval of 3.97.

The safety of the AWD 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 completely resolved by the end of the study. No adverse events were identified as serious or severe. No patients asked to stop the treatment or dropped out of the study due to any adverse event.

Based on the clinical performance as documented in the pivotal clinical study, the Soliton AWD was found to have a safety and effectiveness profile that is similar to the predicate device.

**Summary of Substantial Equivalence**

The AWD and the predicate device have the same intended use and similar indications for use. The use of an accessory to a Q-switched laser to dissipate whitening and allow multiple laser passes in a single session has previously been cleared by FDA for the predicate device. Both the AWD and the PFD patch cause the dissipation and absorption of the gas bubbles that cause whitening. As demonstrated in the performance testing, the AWD device performs similarly compared to the predicate device. Clinical testing confirms that the differences in technology compared to the predicate do not adversely impact performance. Therefore, the AWD is substantially equivalent to its predicate device.

**Conclusions**

Nonclinical and clinical testing of the AWD demonstrated that the device performs as intended with a favorable safety profile. Results in the clinical study were comparable to those reported for the predicate device, in support of substantial equivalence. Therefore, the AWD is substantially equivalent to the predicate device.