September 25, 2022

Zeltiq Aesthetics, Inc.
Saurabh Jamkhindikar
Regulatory Affairs Manager
4410 Rosewood Drive
Pleasanton, California 94588

Re: K222629
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 24, 2022
Received: August 31, 2022

Dear Saurabh Jamkhindikar:

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,

Colin Chen
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: 06/30/2023
See PRA Statement below.

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

K222629

Device Name
Resonic™ Rapid Acoustic Pulse device

Indications for Use *(Describe)*
The 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K222629 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. SUBMITTER: Zeltiq™ Aesthetics, Inc.
4410 Rosewood Drive
Pleasanton, CA 94588

CORRESPONDENT: Mr. Saurabh Jamkhindikar
Regulatory Affairs Manager
Phone: +1 925-241-6299
Cell: +1 213-985-6594
E-mail: saurabh.jamkhindikar@abbvie.com

DATE PREPARED: September 21, 2022

II. DEVICE:

TRADE NAME: Resonic™ Rapid Acoustic Pulse Device

COMMON NAME: Dermatology Laser System

CLASSIFICATION: Class II, 21 CFR §878.4810
Laser surgical instrument for use in general and plastic surgery and in dermatology

PRODUCT CODE: GEX

III. PREDICATE DEVICE: Resonic™ Rapid Acoustic Pulse Device (K212502)

IV. DEVICE DESCRIPTION:

The Resonic™ Rapid Acoustic Pulse (RAP) 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.

V. INTENDED USE:

The 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 one year of observation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The 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 is 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 change the pulse repetition rate for the Cellulite treatment mode from 50Hz as cleared in the predicate to 100Hz for the subject device. 100Hz repetition rate was previously cleared for the tattoo removal treatment mode. With respect to the technology, the software has been modified to allow the 100Hz pulse repetition for the cellulite treatment mode. These changes do not alter the fundamental scientific technology.

In comparison with the predicate device, the following changes have been made on the subject device:

Cellulite Treatment – Pulse Repetition Rate：

- Software only modification to change the pulse repetition rate of the acoustic waves for cellulite treatment mode from 50Hz to 100Hz . This change reduces the treatment time for patients while delivering an equivalent number of pulses and energy per treatment site. The predicate device had 50Hz capability for the Cellulite treatment mode. The 100Hz treatment already exists for tattoo treatment mode, as previously cleared in K212502.

Labeling:

- The Device Labeling and the User Manual was updated to reflect the change in ownership to ZELTIQ Aesthetics, Inc (an AbbVie Company).
- The User Manual was updated to address the 100Hz specification change for Cellulite treatment.

The technological characteristics of the subject device, as outlined in the comparison table below, remain the same as those of the predicate device.

Table 6-1: Technological Characteristics Comparison Table

Device Name	Subject Device Resonic™ Rapid Acoustic Pulse Device 510k pending	Predicate - Soliton Resonic™ Rapid Acoustic Pulse Device (K212502)	Comparison
Indications for Use	The 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 long-term improvement in the appearance of cellulite as supported by clinical data demonstrating treatment benefits up to 1 year of observation.	Indications for Use has been updated to remove the Soliton name as the company was acquired by AbbVie.
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
Waveform	Pulsed	Pulsed	Same
Pulse Repetition Rate	Tattoo: 100 Hz Cellulite: 100Hz	Tattoo: 100 Hz Cellulite: 50Hz	Software only modification to change the pulse repetition rate for Cellulite treatment from 50Hz to 100Hz. The Tattoo Treatment profile already had the 100Hz capability.
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

Device Name	Subject Device Resonic™ Rapid Acoustic Pulse Device 510k pending	Predicate - Soliton Resonic™ Rapid Acoustic Pulse Device (K212502)	Comparison
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 50-60 Hz	240VAC 60 Hz	Same *previous 510k reflected bottom of range, but input power specification remains 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

VII. PERFORMANCE DATA:

Electromagnetic Compatibility and Electrical Safety

The 100Hz change for the Cellulite mode made to the subject Resonic device does not affect the electrical components of the device. The electrical safety testing was repeated for the device as cellulite mode operates at a higher voltage than tattoo mode (2400V vs. 2700V) and consumes more power from the Pulse Power System (PPS). The system was also tested for excessive temperature generation (both at patient-level and component level) at higher frequency. The system was operated at 100Hz, 2700V for safety check. Testing was conducted by SGS testing laboratory, which demonstrated that the device complies with the requirements *under IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*.

Electromagnetic compatibility (EMC) testing for the predicate Resonic device was also conducted by SGS, which demonstrated that the device complies with the requirements under *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 changes made to the subject device do not affect the EMC of the device and the test results on the predicate device remain applicable to the subject Resonic device

Software Verification and Validation Testing
Software regression testing was conducted for the change from 50Hz to 100Hz pulse repetition rate for Cellulite treatment, and the testing results were found to meet the requirements and acceptable for software release. Software testing was conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Cybersecurity
Cybersecurity risk management for the device was performed as part of the overall risk management process for the medical device and follows the guidance in the FDA document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".
The changes made to the predicate device software (K212502) have no impact on cybersecurity.

Biocompatibility Evaluation
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.

Performance Testing - Bench
The subject Resonic device is a modification of the cleared predicate device to allow 100Hz pulse repetition rate change for Cellulite treatment mode. There are no changes to the hardware, electrical components and mechanical design. All other performance bench testing performed on the predicate device is still applicable to the subject Resonic device and demonstrates that the Resonic device performs according to specifications and functions as intended. Individual testing protocols and results were provided in Appendix 6 of the predicate K212502.

Clinical Testing
The Resonic RAP device has been previously cleared for 100Hz Tattoo treatments and 50Hz Cellulite treatments. A bridging study was performed to confirm that the subject device's 100Hz Cellulite treatment mode and the previously cleared 50Hz had comparable performance. The safety of the Resonic RAP device has been previously established based on the adverse events data from the pivotal study results submitted for the predicate device (K212502) and in prior submissions (K201801).

Fifteen female participants ages 18-55 with a mean age of 42.4 were treated with the Resonic Rapid Acoustic Pulse (RAP) device Each participant's left buttock and/or thigh received rapid acoustic pulses at 50 Hz (24 RAP treatment doses) as established with the short-term (12-week) and long- term (>52-week) results used in the previous FDA clearance (K212502). The participant's right buttock and thigh received an equivalent number of rapid acoustic pulses at 100 Hz (12 RAP treatment doses), as subjected in this 510(k).

All adverse events observed in the subject device clinical trial were expected and were categorized as mild or moderate. No unexpected adverse events (UAEs) or serious adverse events (SAEs) related to the device were reported.

The primary effectiveness endpoint for the 100Hz Cellulite treatment study was met as the blinded independent physician assessment (IPA) panel correctly identified post-treatment 50 Hz dose and 100 Hz dose photographs at a rate of 100% and 100%, respectively. The results of the Wilcoxon

matched pairs signed rank test indicated that there was no significant difference between two doses. Table 6-2 summarizes the correct identification results for 50 Hz and 100 Hz treatment doses.

Table 6-2: Cellulite Dose Comparison: 50 Hz and 100 Hz – correct identification of before and after photos

	Cellulite Dose Study 50 Hz Correct ID (2 of 3)	Cellulite Dose Study 100 Hz Correct ID (2 of 3)
Total Subjects	15	15
Correct ID of post-treatment photo	15	15
Incorrect ID of post-treatment photo	0	0
% correct ID of post-treatment photo	100%	100%
Wilcoxon matched pairs signed rank test	**No significant difference**	

The 12-week comparison study results demonstrated that the Cellulite 100 Hz treatment effect with Resonic RAP device in improving the appearance of cellulite is maintained as of the 12-week follow-up after the treatment. Clinical testing confirms that the treatment effect with device at the 100Hz level performs as intended and is equivalent to the treatment effect with the device at 50Hz.

The safety and efficacy of the Resonic device at the 50 Hz for long term improvement in the appearance of cellulite was demonstrated by the pivotal study results submitted for the predicate device (K212502). The pivotal study indicates the similar safety and efficacy outcomes at the time of 12-week follow up and 52-week follow up, accordingly 12-week comparison study is considered to be well representing 52-week outcomes for the Cellulite 100Hz.

Conclusion:

The subject Resonic RAP device and the predicate device have the same intended use, indications for use, technological characteristics and principles of operation. The difference in the Cellulite treatment pulse repetition rate from 50 Hz to 100 Hz does not present different questions of safety or effectiveness as compared to the predicate device.

Nonclinical testing of the device demonstrated that the device performs safely and effectively as intended. Clinical testing confirms that the Cellulite treatment effect with device at the 100Hz is as intended and is similar to the treatment at 50 Hz. There is no impact to the risk profile of the device. The subject Resonic Rapid Acoustic Pulse Device is therefore substantially equivalent to the predicate device.