February 1, 2024

Zeltiq Aesthetics Inc.
Vicky Chai
Director, Regulatory Affairs
4410 Rosewood Drive
Pleasanton, California 94588

Re: K233804
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: December 21, 2023
Received: December 21, 2023

Dear Vicky Chai:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.02.01 13:47:07 -05'00'

Mark Trumbore, Ph.D.
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)*
K233804

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 one year of observation. In addition, the Resonic device can improve the appearance of skin laxity in conjunction with 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.

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.

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K233804
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:

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USA

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DATE PREPARED: Jan. 30, 2024

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 (K222629)

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 and improve the appearance of skin laxity.

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. In addition, the Resonic device can improve the appearance of skin laxity in conjunction with

improvement in the appearance of cellulite.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Resonic™ Rapid Acoustic Pulse device is composed of three parts: the Console, the Handpiece and the replaceable Cartridge. The Console supplies saline to the Handpiece to enable formation of the shock wave within the acoustic pulse chamber. The Handpiece generates acoustic waves in the saline. The acoustic waves pass through the acoustically transparent window of the Cartridge and acoustic ultrasound gel or similar hydrogel pad, which is placed against the surface of the skin to be treated.

The subject Resonic device is identical to the previously cleared Resonic device. No changes have been made to the technological characteristics of the subject device to accommodate the update of indication for use. The primary purpose of this submission is to update the indication for use to reflect that the Resonic device can improve the appearance of skin laxity in conjunction with improvement in the appearance of cellulite, based on data from an independent, blinded review of photographs from an existing study for assessing the safety and effectiveness of Resonic for the improvement in the appearance of cellulite.

VII. PERFORMANCE DATA

To assess the overall clinical improvement in the appearance of skin laxity following treatment with the Resonic device, an independent, blinded physician assessment was performed on baseline and 12-week post- treatment images of lateral, posterior, and posterior oblique views of subjects' treated thighs and buttocks collected from the pivotal study that evaluated the Resonic device for improvement in the appearance of cellulite. The independent, blinded photo assessment study comprised 56 participants, of which all were female, the mean age was 43 years and the majority of the participants were Caucasian.

The primary effectiveness endpoint was defined as the correct identification by at least 2 of 3 blinded reviewers of 12-week post-treatment images with respect to skin laxity from randomized groups of pre-and post-treatment images. The blinded reviewers excluded 5 participants who were not considered as having skin laxity resulting in 51 participants for inclusion in the primary endpoint analysis. The post-treatment images with regards to skin laxity were correctly identified by 2 of 3 blinded reviewers in 90.2% (46/51) of participants, exceeding the 60% prespecified threshold.

The independent, blinded photo assessment demonstrates that when treating cellulite, the Resonic device can improve the appearance of skin laxity in conjunction with improvement in the appearance of cellulite. The visible improvement in cellulite precludes determination of independent improvement in the appearance of skin laxity as stand-alone primary outcome.

VIII. CONCLUSION

The Resonic device and its predicate device have the same intended use and similar indications for use, the same technological characteristics and principles of operation. Clinical testing confirms the treatment effect with the Resonic device in improving the appearance of skin laxity in conjunction with improvement in the appearance of cellulite. Therefore, the Resonic device is substantially equivalent to the predicate device.