November 1, 2017

ZELTIQ Aesthetics, Inc.
Ewald Riechert
Director of Regulatory Affairs
4410 Rosewood Road
Pleasanton, California 94588

Re: K172144
Trade/Device Name: ZELTIQ CoolSculpting System
Regulation Number: 21 CFR 878.4340
Regulation Name: Contact Cooling System for Aesthetic Use
Regulatory Class: Class II
Product Code: OOK
Dated: September 28, 2017
Received: September 29, 2017

Dear Ewald Riechert:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172144

Device Name
Zeltiq CoolSculpting System

Indications for Use *(Describe)*

The CoolSculpting System is a skin cooling or heating device. The device is indicated for cold-assisted lipolysis (breakdown of fat) of the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen, and flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen and flank. When used for cold-assisted lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area.

Cooling with the device may also be used to minimize pain and thermal injury during laser and dermatological treatments and act as a local anesthetic for procedures that induce minor local discomfort.

The CoolSculpting System is also indicated for use to provide localized thermal therapy (hot or cold) to minimize pain post-trauma and post-surgery, and for temporary relief of minor aches, pains, and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm and for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The ZELTIQ Pretreatment Skin Wipe and Gel/Gelpad facilitate thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact.

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."

5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

CONTACT:
Ewald Riechert
Director of Regulatory Affairs
ZELTIQ Aesthetics, Inc.
Phone: 925-568-2977

DATE PREPARED: July 14, 2017

II. DEVICE:

TRADE NAME: ZELTIQ CoolSculpting System

COMMON NAME: Skin Cooling Device

CLASSIFICATION NAME: Contact Cooling System for Aesthetic Use

DEVICE CLASSIFICATION: Class II, 21 CFR §878.4340

PRODUCT CODE: OOK

III. PREDICATE DEVICES:

Predicate Device: CoolSculpting System (K171069, OOK)
Reference Device: Ulthera System (K121700, OHV)

IV. DEVICE DESCRIPTION:

The CoolSculpting System is a portable thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The CoolSculpting System is comprised of a control unit, detachable vacuum and surface applicators and supplies such as liners, gel/gelpads, cycle cards, geltraps, gaskets, foam borders and securement system.

V: INDICATION FOR USE:

The CoolSculpting System is a skin cooling or heating device. The device is indicated for cold-assisted lipolysis (breakdown of fat) of the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen, and flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen and

flank. When used for cold-assisted lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area.

Cooling with the device may also be used to minimize pain and thermal injury during laser and dermatological treatments and act as a local anesthetic for procedures that induce minor local discomfort.

The CoolSculpting System is also indicated for use to provide localized thermal therapy (hot or cold) to minimize pain post-trauma and post-surgery, and for temporary relief of minor aches, pains, and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm and for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The ZELTIQ Pretreatment Skin Wipe and Gel/Gelpad facilitate thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The ZELTIQ CoolSculpting System is the same as the device cleared in K171069. No changes have been made to the device to accommodate this new indication.

The CoolSculpting System has been established as safe and effective through many prior clearances (the most recent is K171069). It was demonstrated to be safe and effective for the submental area in K151179.

VII. PERFORMANCE DATA:

Biocompatibility testing

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K171069).

Electrical safety and electromagnetic compatibility (EMC)

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K171069).

Software Verification and Validation Testing

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K171069).

Performance testing

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K171069).

Clinical Study

ZELTIQ conducted a retrospective photo analysis study examining the effectiveness of the cryolipolysis system to affect the appearance of lax tissue in the submental area. The photographic analysis was based on the methodology used to obtain clearance of the reference device (Ulthera System, K121700).[1]

Sixty subjects were enrolled in an original IDE approved study that was used for the submental clearance in K151179. Two of the 60 subjects did not receive full treatments and were excluded from the per-protocol population. Subjects received treatment with the ZELTIQ CoolSculpting System on the submental area, and were followed through a 12-week post-treatment visit.

The primary safety endpoint in the original IDE approved study was met and remains unchanged since the close of the study and was previously submitted in K151179.

The primary effectiveness endpoint in the original IDE involved independent panel review of pre- and 12-week post-treatment photographs of the treatment area. For the per protocol population, the correct baseline photograph identification rate by the independent panel reviewers was 91.4%. This data remains unchanged since the close of the study and was previously submitted in K151179.

The secondary effectiveness endpoint for subject satisfaction was assessed by an IRB-approved questionnaire administered at 12-week post-treatment. Seventy-five percent of the subjects reported that they agree or strongly agree that the treatment made their chin look more toned. This data remains unchanged since the close of the study and was previously submitted in K151179.

This retrospective study used the per-protocol population (n=58) for analysis. One subject was excluded from the analysis due to excessive hair in the submental region, therefore the number of subjects used for analysis was 57. Right and left lateral photographic views of the submental area taken at baseline and at the 12-week post final treatment visit were included in the analysis. Each photo was cropped and masked prior to evaluation. A board certified plastic surgeon identified the following anatomical points on each photograph: the lateral canthus, the anterior most point where the nostril meets the columella, and the point where the chin meets the neck (submental crease). A series of lines were drawn on the photo using AutoCAD software and areas in the submental region were measured. A responder analysis was performed with the criteria being ≥ 20 mm^2 decrease in area as measured on both the right lateral and left lateral views of the region. A second analysis was performed comparing the responders with results from the independent physician review panel of photos conducted for the previous study.

[1] Oni, G, Hoxworth R, Teotia, S, et al. Evaluation of a Microfocused Ultrasound System for Improving Skin Laxity and Tightening in the Lower Face. *Aesthetic Surgery Journal* 2014;34(7):1099-1110.

Further evidence of treatment effectiveness found the data from photographic analysis of the treated areas indicates 77.2% (44/57) of subjects exhibited a ≥ 20 mm^2 area reduction in the submental area and neck. Of those 44 subjects, 42 (95.5%) were correctly identified by the physician panel as having a visible response. The results of this photographic analysis indicate that the CoolSculpting procedure on the submental area can also affect the appearance of lax tissue in the submental area.

The study design and results are summarized in the table below:

Table 5.1. Summary of Retrospective Study for effect on the appearance of lax tissue in the Submental area

Study Design	Retrospective
Sample Size for analysis	57
Effectiveness Results	The per protocol population consisted of all the treated subjects followed for 12 weeks with weight change of no more than 5% of total body weight at the time the 12 week images were taken. For the per protocol population, the correct baseline photograph identification rate by the independent panel reviewers was 91.4%. Data from photographic analysis showed effect on the appearance of lax tissue (≥ 20 mm^2) from baseline to 12 weeks post-treatment in 77.2% (44/57) of subjects. Of those 44 subjects, 42 (95.5%) were correctly identified by the physician panel as having a visible response. Subject satisfaction data from original IDE: 75% of the subjects reported that they agreed that the treatment made their chin look more toned.
Safety Results	The primary safety endpoint of the original IDE approved study was met and remains unchanged since the close of the study. All device- and/or procedure-related adverse events have resolved spontaneously.

The data provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence of the CoolSculpting System for the additional indication for use of affecting the appearance of lax tissue in the submental area.

VIII. CONCLUSION:

The ZELTIQ CoolSculpting System is the same as the device cleared in K171069. No changes have been made to the device to accommodate this indication of affecting the appearance of lax tissue in the submental area.

The CoolSculpting System is substantially equivalent to the predicate device for the revised indications for use. The clinical data shows visible effect in the appearance of lax tissue meeting both the safety and effectiveness endpoints.

The CoolSculpting System has been established as safe and effective through many prior clearances (the most recent is K171069). It was demonstrated to be safe and effective for the submental area in K151179.

The CoolSculpting System has not changed to accommodate this expanded indication. The clinical data indicates the same safety and effectiveness for the CoolSculpting System for this expanded intended use. As such, the CoolSculpting System is substantially equivalent to the predicate device (previously cleared CoolSculpting System, K171069).