DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 21, 2016

Zeltiq Aesthetics, Inc
Ms.Shruti Jayakumar
Senior Regulatory Affairs Manager
4698 Willow Road
Pleasanton, California 94588

Re: K162050
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: October 20, 2016
Received: October 21, 2016

Dear Ms. Jayakumar:

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 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 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 -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162050

Device Name
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.

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.

510(K) SUMMARY

COOLSCULPTING SYSTEM

Submitted by: ZELTIQ™ Aesthetics, Inc.
4410 Rosewood Drive
Pleasanton, CA 94588

CONTACT: Shruti Jayakumar
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ZELTIQ Aesthetics, Inc.
Phone: 925-474-2516
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DATE PREPARED: November 21, 2016

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

PREDICATE DEVICES: The ZELTIQ CoolSculpting System (K160259)

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.

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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.

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, foam borders and securement system.

TECHNOLOGICAL CHARACTERISTICS:
The CoolSculpting System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. This submission expands the CoolSculpting System's indications for use to include treatment of the upper arm and also introduces a new vacuum applicator known as CoolAdvantage.
This CoolSculpting features vacuum applicators of various sizes and non-vacuum surface applicators that are intended to provide clinicians with an additional option when treating a flat area of the body.
As part of its suite of vacuum applicators, ZELTIQ has also developed a new applicator known as CoolAdvantage. CoolAdvantage has the same cup design as CoolMini and features interchangeable contours to accommodate body areas of different curvature. The contours are in the shapes of previously cleared vacuum applicators (CoolCurve+, CoolFit, and CoolCore cleared in DEN090002 and K133212). The treatment parameters for CoolAdvantage are within the previously cleared parameters for vacuum applicators (K142491). Treatment of the upper arm is cleared for -11°C for 35 minutes.

SUMMARY OF SUBSTANTIAL EQUIVALENCE:
The ZELTIQ CoolSculpting System is substantially equivalent to the device cleared in K160259. Clinical data demonstrates that cold-assisted lipolysis of the upper arms is substantially equivalent to cold-assisted lipolysis of the abdomen, flanks, thighs, submental area, back fat, bra fat, and banana roll which were cleared under K160259.

As stated previously, this submission also introduced a new vacuum applicator known as CoolAdvantage. CoolAdvantage has the same cup design as CoolMini and features interchangeable contours to accommodate body areas of different curvature. The contours are in the shapes of previously cleared vacuum applicators (CoolCurve+, CoolFit, and CoolCore cleared in DEN090002 and K133212). The CoolAdvantage applicator is also provided with disposable gaskets which provide a tight seal between the applicator cup and the contour. The treatment parameters for CoolAdvantage are within the previously cleared parameters for vacuum applicators (K142491). Treatment of the upper arm is cleared for -11°C for 35 minutes.

Clinical data: ZELTIQ conducted a clinical investigation to evaluate the safety and efficacy of cryolipolysis for non-invasive reduction of upper-arm fat. In this study, 30 subjects were enrolled at two clinical sites. Sixty initial treatments were performed with a prototype CoolAdvantage applicator (CoolFit applicator with aluminum Insert). The average age of the 30 subjects enrolled in the study was 45.7 years with an average Body Mass Index (BMI) of 28.2. All subjects were female. Each subject was treated once on each upper arm, at -11°C for 35 minutes. Follow-up data is available through 12 weeks post-treatment. Subject safety was assessed throughout the study. Follow-ups were required at 1 week, 4 weeks, and 12 weeks post-treatment. All 30 subjects completed the 12 week follow-up.

The primary safety endpoint was the incidence of unanticipated adverse device effects. Clinical safety assessment showed anticipated side-effects. There were 4 patients with prolonged numbness lasting greater than 12 weeks. No unanticipated adverse device effects, or serious device or procedure-related adverse effects occurred. All device- and/or procedure-related adverse events have resolved spontaneously.

The primary efficacy endpoint involved independent panel review of pre- and 12-Week post-treatment photographs of the treatment area for discernible fat layer reduction. 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 85.2% [72.9%, 93.4%].

Further evidence of treatment efficacy is found in the data from ultrasound measurements of fat reduction at the treated areas, with significant reduction in the fat layer (0.32 cm) from baseline to 12 weeks post-treatment.

The secondary efficacy endpoint for subject satisfaction was assessed by an IRB-approved questionnaire administered at 12 weeks post-treatment. 72.41% of the subjects found the procedure to be comfortable to very comfortable, and 63.3% of the subjects reported that they would recommend the procedure to a friend.

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

Study Design	Prospective, multicenter, non-randomized, interventional cohort study
Sample Size	30 subjects treated on both upper arms (60 treatments total) across two clinical sites
Principal Eligibility Criteria	• Clearly visible fat sufficient for treatment on the upper arm • No weight change exceeding 5% in the preceding month • Male or female subjects between 22 and 65 years of age
Follow up Intervals	1 week, 4 weeks, and 12 weeks
Endpoints	Primary endpoints: • Safety endpoint – Rate of unanticipated adverse device effects (UADE).

	• Efficacy endpoint: Correct identification pf pre-treatment vs 12 Week post-treatment images by at least two out of three blinded, independent reviewers Secondary endpoints: • Subject satisfaction as assessed by questionnaire administered at 12 weeks post-treatment • Change in ultrasound-measured upper arm fat from pre-treatment to 12 weeks post-treatment
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 85.2% [72.9%, 93.4%]. Data from ultrasound measurements showed significant reduction in the fat layer (0.32 cm) from baseline to 12 weeks post-treatment. Subject satisfaction: 72.41% of the subjects found the procedure to be comfortable to very comfortable, and 63.3% of the subjects reported that they would recommend the procedure to a friend.
Safety Results	Clinical safety assessment showed anticipated side-effects. There were 4 patients with prolonged numbness lasting greater than 12 weeks. All adverse events have resolved. No unanticipated adverse device effects, or serious device or procedure-related adverse effects occurred. All device- and/or procedure-related adverse events have resolved spontaneously.

This clinical investigation demonstrates that use of the ZELTIQ CoolSculpting System can safely and effectively induce cold-assisted lipolysis as the predicate device.

CONCLUSION:

Testing of the CoolSculpting System, which includes the CoolAdvantage applicator, demonstrated that the device performs as intended. As such, the CoolSculpting System with CoolAdvantage applicator is substantially equivalent to the predicate device.