DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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ZELTIQ™ Aesthetics Incorporated
Ms. Shruti Jayakumar
Regulatory Affairs Manager
4698 Willow Road
Pleasanton, California 94588

September 24, 2015

Re: K151179
Trade/Device Name: CoolSculpting System
Regulation Number: 21 CFR 878.4340
Regulation Name: Contact cooling system for aesthetic use
Regulatory Class: Class II
Product Code: OOK
Dated: July 13, 2015
Received: July 14, 2015

Dear Ms. Jayakumar:

This letter corrects our substantially equivalent letter of September 22, 2014.

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" (21CFR 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 yours,

Joshua C. Nipper -S

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)*
K151179

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 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 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.

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"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

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

APPLICANT: ZELTIQ™ Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

CONTACT: Shruti Jayakumar
Regulatory Affairs Manager
ZELTIQ Aesthetics, Inc.
Phone: 925-474-2516
Fax: 925-474-8028

DATE PREPARED: August 21, 2015

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 (DEN090002, K120023, K133212, K142491)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CoolSculpting System is a portable thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The CoolSculpting System consists of a control unit, detachable vacuum and surface applicators, as well as supplies such as liners, gelpads, skin wipes, cycle cards, foam borders and securement system, and software which includes functions to collect patient data, monitor tissue during cooling and minimize the risk of damage to tissue.

SUBSTANTIALLY EQUIVALENT TO:

The ZELTIQ CoolSculpting System is substantially equivalent to the ZELTIQ Dermal Cooling Device, also known as the ZELTIQ CoolSculpting System, which has been cleared for the indication of cold-assisted

lipolysis of the flank (love handle) under DEN090002, for the abdomen under K120023, and for the thighs under K133212. It has also been cleared for flexible treatment parameters under K142491.

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 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 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.

TECHNICAL CHARACTERISTICS:

The CoolSculpting System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site with option for vacuum to hold tissue and or massage to temporarily improve local circulation. The applicators, foam borders, gel, gelpads, liners, pretreatment skin wipes, and securement systems are patient-applied parts.

Sensors in the applicator panels monitor the skin surface, providing feedback that controls the rate of heat flux. The pretreatment skin wipes and gel/gelpad protect the skin by providing thermal coupling at the interface between the applicator panels and the skin. Cards provide cycles and profiles for use with the system. The system monitors tissue during cooling and employs multiple safety features including the Freeze Detect® system, to minimize the risk of damage to tissue. To accommodate the submental treatment site, the system includes the CoolMini applicator. In addition, proprietary skin wipes have been introduced to improve contact to skin. The CoolSculpting System has vacuum applicators of various sizes and a non-vacuum surface applicator that is intended to provide clinicians with options when treating different areas of the body. The technological characteristics are the same as the predicate devices. All share the same mechanism of cooling and heating for the same intended use.

PERFORMANCE DATA:

Studies have demonstrated the use of the CoolSculpting System on the submental area (this 510k), thighs (K133212), abdomen (K120023), and flanks (DEN090002).

ZELTIQ Clinical Studies

The table below describes the results from the submental area IDE study. Data supporting the previously cleared indications can be found in the 510(k) summaries listed above.

Submental Area Study

Study Design	The ZELTIQ System is a medical device intended for use as a non-invasive

	aesthetic treatment for the reduction of subcutaneous fat. This study was FDA approved under IDE G140083 and was intended to evaluate the safety and efficacy of cryolipolysis for non-invasive reduction of submental fat. The study protocol was approved by IRB. This study was a prospective, multi-center, open label, non-randomized, interventional cohort study. Sixty (60) subjects were enrolled at three clinical sites. Male or female subjects between 22 and 65 years of age, with submental skin fold thickness greater than 1cm were eligible to participate. Subjects were treated on the submental area at least once, with the option of a second treatment 6 weeks after the first. Subject safety was assessed throughout the study, including immediately post treatment, and at the subsequent 1-week, 6-week and 12-week post-final treatment follow-up visits.
Inclusion Criteria	a) Male or female subjects $\geq$ 22 years of age and $\leq$ 65 years of age. b) Submental skin fold thickness > 1cm (measured by caliper). c) No weight change exceeding 5% of body weight in the preceding month. d) Agreement to maintain his/her weight (i.e., within 5%) by not making any major changes in diet or exercise routine during the course of the study. e) Subject has signed a written informed consent form.
Exclusion Criteria	a) Skin laxity in the neck or chin area for which reduction in submental fat may, in the opinion of the investigator, result in an unacceptable aesthetic result. b) Prominent platysmal bands at rest which may interfere with assessment of submental fat c) Evidence of any cause of enlargement in the submental area other than localized subcutaneous fat, such as swollen lymph nodes or ptotic submandibular glands. d) Significant enlargement on the anterior neck that may prevent the proper placement of the applicator e.g. enlarged thyroid glands. e) Treatment with dermal fillers, radiofrequency or laser procedures, or chemical peels in the neck or chin area (below the mandible) within the past 6 months. f) Botulinum toxin or other aesthetic drug injections within the neck or chin area (below the mandible) within the past 6 months. g) History of facial nerve paresis or paralysis (such as Bell's palsy). h) History of a fat reduction procedure (e.g., liposuction, surgery, lipolytic agents, etc.) or implant in or adjacent to the area of intended treatment. i) History of prior neck surgery, or prior surgery in the area of intended treatment. j) Current dental infection. k) Known history of cryoglobulinemia, cold urticaria, or paroxysmal cold hemoglobinuria. l) Known history of Raynaud's disease, or any known condition with a response to cold exposure that limits blood flow to the skin. m) History of bleeding disorder or is taking any medication that in the investigator's opinion may increase the subject's risk of bruising. n) Currently taking or has taken diet pills or weight control supplements within the past month. o) Any dermatological conditions, such as scars in the location of the treatment

	area that may interfere with the treatment or evaluation. p) Active implanted device such as a pacemaker, defibrillator, or drug delivery system. q) Pregnant or intending to become pregnant in the next 6 months. r) Lactating or has been lactating in the past 6 months. s) Unable or unwilling to comply with the study requirements. t) Currently enrolled in a clinical study of an unapproved investigational drug or device. u) Any other condition or laboratory value that would, in the professional opinion of the investigator, potentially affect the subject's response or the integrity of the data or would pose an unacceptable risk to the subject.
Study protocol	Sixty initial treatments were performed with the prototype CoolMini vacuum applicator; 59 Fifty-nine (59) subjects were re-treated at the 6-week follow-up visit. Treatments were performed at -10°C for 60 minutes. Follow-up data is available through 12 weeks post-treatment. Subject safety was assessed throughout the study. Two of the subjects in the group who received 2 cooling cycles received a partial cooling cycle due to device interference. Therefore, the per-protocol sample size for the primary photographic efficacy endpoint analysis is 58.
Demographics	Average age was 49.3 years (range from 25 and 61). Forty-eight (48) of the subjects enrolled in the study were female and twelve were male. Average BMI was 31.8 (range from 23.3 to 46.2). Average weight was 196.1 pounds (range from 139.2 to 285.6). Ethnicity: Caucasian, Hispanic, African American, Other
Study endpoints	The primary safety endpoint was the incidence of device- and/or procedure-related adverse events. The primary efficacy endpoint involved independent panel review of pre-treatment and 12-week post-final treatment photographs of the treatment area for discernible fat layer reduction. Secondary endpoints included the reduction in fat layer thickness as measured by ultrasound at 12 weeks post-final treatment and subject satisfaction as assessed by a questionnaire administered at 12 weeks post-final treatment.
Results	The primary safety endpoint was the measurement of all device- or procedure-related adverse events. All adverse events reported during and after the treatment were included in the safety analysis. The primary safety endpoint was met. Per the protocol definitions, there were no device- or procedure-related adverse events that were categorized as serious adverse events (SAE) or unanticipated adverse device effects (UADE). There were four device- and/or procedure-related adverse events, which consisted of two (2) incidents of prolonged erythema, one (1) incident of hyperpigmentation, and one (1) incident of subject report of fullness sensation in back of throat due to swelling. All adverse events resolved by the final follow-up at 12 weeks post-final treatment visit. Four device- or procedure-related adverse events were reported and have resolved. Clinical safety assessment showed anticipated and transient side-effects, all of which resolved over the course of the study. Immediately post-

	treatment, the most common events within the treatment area were erythema, edema, and numbness. At the 1-week follow-up visit, most incidences of erythema and edema had resolved and numbness was the most prevalent side effect. By the 6-week follow-up visit post-treatment #1, four incidences of mild numbness were reported. At the 6-week follow-up visit post-treatment #2, two incidences of mild numbness were reported. By the 12-week post-final treatment visit, all adverse events had resolved. The safety data recorded during this study supports the safety of the treatment parameters and device investigated. The primary efficacy endpoint was correct identification of pre-treatment vs. 12-week post-final treatment images by 3 blinded independent reviewers. The overall correct identification rate by the 3 reviewers was 91% for the per-protocol population (n=58), which met the pre-established 80% criterion for success. The primary efficacy endpoint was met. Reduction in subcutaneous fat layer thickness as measured by ultrasound at 12-weeks post-final treatment was a secondary efficacy endpoint for this study. Analysis of the per-protocol data (57 subjects) showed a statistically significant ($p<0.0001$) reduction of 0.20 cm. Therefore, the secondary efficacy endpoint for statistically significant reduction of fat layer thickness was met. The secondary efficacy endpoint for subject satisfaction was assessed by a questionnaire administered at 12 weeks post-final treatment. Overall, 83% of subjects enrolled in the study indicated they were satisfied with the treatment and 80% reported that they would recommend the treatment to a friend.
Conclusions	These clinical findings demonstrate that use of the CoolSculpting System for treatment of the submental area is substantially equivalent to treatments of the previously cleared areas of the flanks, abdomen, and thighs.