DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 26, 2015

ZELTIQ™ Aesthetics Incorporated
Shruti Jayakumar
Senior Regulatory Affairs Specialist
4698 Willow Road
Pleasanton, California 94588

Re: K142491
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: December 29, 2014
Received: December 30, 2014

Dear Ms. Shruti 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" (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,

David Krause -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)*
K142491

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 of the 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 the thigh, abdomen and the 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 Gelpad facilitates 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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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.

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

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

DATE PREPARED: September 3, 2014

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)

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 is comprised of a control unit, detachable vacuum and surface applicators and supplies such as liners, gelpads, cycle cards, foam borders and securement system.

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.

Clinical testing has demonstrated the ability of the CoolSculpting System to cause lipolysis of the subcutaneous fat in the treatment area with flexible treatment parameter ranges in the same way as the predicate device. The mechanism of action remains the same regardless of temperature or treatment duration. The flexible parameters do not raise new issues of safety or effectiveness.

INDICATION FOR USE:
The CoolSculpting System is a skin cooling or heating device. The device is indicated for cold-assisted lipolysis of the 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 the thigh, abdomen and the 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 Gelpad facilitates 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. This system features vacuum applicators of various sizes and a non-vacuum surface applicator that is intended to provide clinicians with an additional option when treating a flat area 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:
ZELTIQ conducted an IRB-approved non-significant risk clinical study to evaluate the safety and efficacy of the CoolSculpting System with flexible treatment parameter ranges. The study enrolled 45 subjects who received up to two treatments on the flank in one visit. Follow-up was conducted until 16 weeks post-treatment. Subjects were assessed for efficacy via ultrasound and comparison of before and after photographs.

The primary efficacy endpoint of reduction in fat layer thickness was met. Analysis of ultrasound data showed statistical significance ($p<0.0001$) for both the as-treated population and per-protocol population. The secondary efficacy endpoint of correct identification of pre- vs 16-week post-treatment images was met. The correct photo pair identification rate was 86% for the per-protocol population, with 85% of all photo pairs being correctly identified by at least two out of three reviewers. The secondary efficacy endpoint of subject satisfaction was also met. For the as-treated population, 88.37%

reported being moderately or very satisfied with the CoolSculpting procedure. The primary safety endpoint of device and/or procedure-related adverse events was met. Adverse events included numbness, pain, and hyperpigmentation. One treatment was not completed due to a first degree burn. Three cases of numbness lasted beyond the 16 week follow-up and all three had resolved within 19 days of their respective 16-week visits. All device and/or procedure-related adverse events were mild or moderate in nature and all have resolved.

The materials used in this device are the same as previously cleared in DEN090002, K120023, and K133212. No new biocompatibility risks have been identified.