DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 23, 2016

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

Re: K160259
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: January 29, 2016
Received: February 1, 2016

Dear 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 and Part 809); 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 and Part 809), 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 yours,

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)*
K160259

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 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

DATE PREPARED: March 14, 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 (K151179)

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, gel/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), abdomen, thighs and submental area (K151179).

Clinical data from ZELTIQ and data from published scientific literature indicates that the CoolSculpting System has the same mechanism of action regardless of treatment site. The safety and efficacy profile remains the same.

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 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 bra fat, back fat, banana roll, submental area, thigh, abdomen and flank.

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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. This system 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. The technological characteristics are the same as the predicate devices. All share the same mechanism of cooling and heating for the same intended use. There is no change required to the device to accommodate additional treatment sites. The device is the same as has been previously cleared.

PERFORMANCE DATA:
A review of clinical publications revealed 4,792 cryolipolysis treatments during clinical studies. From these studies, we compiled the numbers of treatments in several anatomical areas: 1,695 treatments in the abdomen, 1,987 treatments in the flanks, 501 treatments in the back, 323 treatments in the inner thigh, 150 treatments in the lateral thigh, 3 treatments in the anterior thigh, 119 treatments in the submental area, and 14 treatments in the banana roll region.

Efficacy was measured by several techniques including ultrasound and caliper measurements, circumferential measurements, 3D quantification of volume reduction, and blinded, independent review of clinical photographs. Based on the compilation of data from these studies, the overall mean

ultrasound fat layer reduction ranged from 10.3 to 25.5% and 1.9 to 8.3 mm. Compiled mean caliper fat layer reduction ranged from 14.7 to 23.0%. Single studies showed mean 0.9 cm circumferential reduction in the inner thigh, 2.4 cm circumferential reduction in the flanks, 6.8 cm circumferential reduction in the abdomen, and 39.6 cm^3 volumetric reduction in the flanks.

Based on the compilation of these various studies, the overall mean ultrasound fat layer thickness reduction was 20.6% and 3.9 mm. Compiled mean caliper fat layer reduction was 22.3%. The independent photo review was 89.7% correct, on average.

As shown by multiple clinical studies submitted for clearance to the agency, the summary of published data shows a similarly high safety and efficacy profile for the cryolipolysis procedure. Common procedural side effects include erythema, bruising, and numbness, which typically resolve within one month of treatment. Based on the literature review, 6 cases would be considered serious adverse events. These serious adverse events include three cases of paradoxical hyperplasia in the abdomen, one case of paradoxical hyperplasia in the abdomen, back, and flanks, one case of contour irregularity in the abdomen, and one case of contour irregularity in the flank. For 4,792 treatments in published studies, the incidence of serious adverse events is very low (0.13%). Given the fact that 76.8% of treatments were to the abdomen and flanks, this incidence rate shows no clear indication of treatment site specificity. The clinical publications indicate that cryolipolysis is a safe and effective non-surgical procedure for subcutaneous fat reduction.