APR 09 2014

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
ZELTIQ Aesthetics, Inc.
Phone: 925-621-2516
Fax: 925-621-7376

DATE PREPARED: April 7, 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 device (K080521 and K120023)

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 applicators and supplies such as liners, gelpads, and cycle cards.

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 K080521 and for the abdomen under K120023.

Clinical testing has demonstrated the ability of the CoolSculpting System to cause lipolysis of the subcutaneous fat in the thigh in the same way that lipolysis occurs when the device is used in the flank

and abdomen. The applicators all share the same technological characteristics, mechanism of action, and intended use.

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 belt 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:

Clinical testing demonstrates that the CoolSculpting System can cause lipolysis with a subsequent removal of fat. Clinical results for the flank, abdomen, and thigh, support the safe and effective use of the device for this indication.

ZELTIQ conducted two clinical investigations to determine the safety and efficacy of cold-assisted lipolysis in the thigh region. In the inner thigh study, 90 treatments were completed with the flat cup vacuum applicator; in the outer thigh study, 40 treatments were completed with the belt applicator. Follow-up data is available for both studies up to 16 weeks post-treatment. Three blinded evaluators assessed the photos for visible reduction of fat in the treatment areas at the 16-week follow-up visit. The evaluators were presented with the series of photographs and were asked to identify the pre-treatment photographs for each subject.

The overall correct identification rate by the three evaluators was 90.5% for the inner thigh study and 83.9% for the outer thigh study. At least two out of three evaluators correctly identified 90.5% of all

photo pairs for the inner thigh study and 87.1% for the outer thigh study. The results demonstrate that the ZELTIQ CoolSculpting System affects the appearance of the thighs.

Adverse events reported during the studies included numbness and mild contour irregularity. All adverse events but one resolved by the 16 week follow-up. A mild case of hyperpigmentation in the treatment area persisted beyond the 16 week follow-up. This is a rare side effect that typically resolves spontaneously. The clinical investigations demonstrate that use of the ZELTIQ CoolSculpting System can safely and effectively induce cold-assisted lipolysis in the thigh in the same manner as in the abdomen and flanks.

The materials used in this device are the same as previously cleared in K080521 and K120023. No new biocompatibility risks have been identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

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

Re: K133212
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: February 21, 2014
Received: February 24, 2014

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133212

Device Name: ZELTIQ CoolSculpting

Indications 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.

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The ZELTIQ Gelpad facilitates thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact.

Prescription Use __x____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S