



Food and Drug Administration
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July 7, 2017

ZELTIQ Aesthetics, Inc.
Mr. Ewald Riechert
Director of Regulatory Affairs
4410 Rosewood Road
Pleasanton, California 94588

Re: K171069

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: April 7, 2017
Received: April 10, 2017

Dear Mr. Riechert:

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 -S3**

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171069

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.

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[ZELTIQ CoolSculpting System - 510(k) Summary - K171069]**6. 510(K) SUMMARY**

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

I. SUBMITTER: ZELTIQ™ Aesthetics, Inc.
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Pleasanton, CA 94588

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Director of Regulatory Affairs
ZELTIQ Aesthetics, Inc.
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DATE PREPARED: April 7, 2017

II. DEVICE:

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

III. PREDICATE DEVICE: The ZELTIQ CoolSculpting System (K162050)

IV. 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, gaskets, foam borders and securement system.

As part of the CoolSculpting System suite of applicators, ZELTIQ has developed two new vacuum applicators known as CoolAdvantage Plus and CoolAdvantage Petite. Both applicators feature the curved aluminum cup design with interchangeable silicone contours that is identical to the previously cleared CoolAdvantage applicator (K162050). They have been modified in size to accommodate different sizes of fat bulges. All other technological characteristics, including

[ZELTIQ CoolSculpting System - 510(k) Summary - K171069]

mechanism of action, and performance remain identical for the CoolAdvantage family of applicators.

The CoolAdvantage family of applicators is also provided with a new gelpad known as CoolAdhesive Pad. The CoolAdhesive Pad is comprised of fructose and glycerin in a pad made of rayon and spandex. This material is commonly used in the garment industry. It has the identical functionality as the previously cleared gelpads and is intended to provide consistent thermal contact during treatments with the CoolAdvantage family of applicators. Fructose and glycerin are considered safe ingredients and are found in commonly used products. Fructose is generally used as a food additive and glycerin is typically found in common cosmetic products such as lotion and soap. Glycerin is generally recognized as safe (GRAS per CFR §182.1320). The CoolAdhesive Pad has been tested for biocompatibility and is considered biocompatible. The performance remains the same for CoolAdhesive Pad as for the previously cleared gelpads.

V. INDICATION FOR USE:

The indications for use are unchanged from the legally marketed device, the CoolSculpting System (K162050).

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.

[ZELTIQ CoolSculpting System - 510(k) Summary - K171069]**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

The ZELTIQ CoolSculpting System is the same as the device cleared in K162050. The indication and mechanism of action remain identical. This submission includes two new applicators, CoolAdvantage Plus and CoolAdvantage Petite. The CoolAdvantage Plus and CoolAdvantage Petite applicators are the same as the previously cleared CoolAdvantage applicator (K162050). Both applicators have the identical curved cup design with interchangeable contours as the previously cleared CoolAdvantage applicator (K162050). They have been modified in size to accommodate different bulges of fat. The dimensions of the applicators are within previously cleared specifications. The CoolAdvantage Plus applicator is provided with a treatment profile of -11°C for 45 minutes and the CoolAdvantage Petite is provided with a treatment profile of -11°C for 35 minutes. Both profiles are within previously cleared treatment parameters (K142491).

In addition, this submission includes a new gelpad known as CoolAdhesive Pad. CoolAdvantage Plus is provided with a larger version of this gelpad, known as CoolAdhesive Plus Pad. The CoolAdhesive Pad has the identical intended use to the previously cleared gelpads (K162050) and is intended to facilitate thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact. It has the identical duration of contact (less than 24 hours) and is used on intact skin during treatments. The CoolAdhesive Pad is comprised of fructose and glycerin in a pad made of rayon and spandex. This material is commonly used in the garment industry. Fructose and glycerin are considered safe ingredients and are found in commonly used products. Fructose is generally used as a food additive and glycerin is typically found in common cosmetic products such as lotion and soap. Glycerin is generally recognized as safe (GRAS per CFR §182.1320). The pad has been tested for biocompatibility and is considered biocompatible.

VII. PERFORMANCE DATA:

The following performance data were generated in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and international Standard ISO10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The CoolSculpting System is considered a skin contacting surface device for a limited duration of (\leq 24hours). The following tests were conducted: Cytotoxicity, Sensitization, and Irritation.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Zeltiq CoolSculpting System, consisting of the control unit and the detachable vacuum and surface applicators. The system complies with the IEC 60601-1 (2005+A1:2012) standard for safety and the IEC 60601-1-2 (2007) standard for EMC.

[ZELTIQ CoolSculpting System - 510(k) Summary - K171069]**Software Verification and Validation Testing**

The new applicators CoolAdvantage Plus and CoolAdvantage Petite use the same software as the predicate applicator CoolAdvantage. There is no change to the Control Unit and the GUI since the workflow remains identical to the predicate. Software verification and validation testing were conducted per FDA's "General Principles of Software Validation: Final Guidance for Industry and FDA Staff" (January 2002).

The software for this device is considered a moderate level of concern.

Performance testing

Bench testing to controlled protocols, with calibrated equipment, was used to demonstrate the ability of the CoolSculpting System to meet performance specifications, and to demonstrate substantial equivalence. These tests included design verification, usability, and surface temperature measurements.

Verification testing was completed to demonstrate:

- thermal performance
- thermal range
- reuse
- physical specifications
- compatibility with use environment
- treatment parameters (i.e. minimum and maximum temperature settings, treatment duration, active cooling and warming)
- power and operational control
- labeling, interface, and support requirements

All design verification and validation tests were passed successfully by meeting the acceptance criteria.

Clinical Studies

No preclinical or clinical testing was performed.

VIII. CONCLUSION:

The intended use, mechanism of action, technical characteristics and performance of the new CoolAdvantage Plus and CoolAdvantage Petite applicators are the same as the previously cleared CoolAdvantage applicator (K162050). The CoolAdhesive Pad family has the identical intended use, mechanism of action, and performance as the previously cleared CoolGel and CoolGel Max gelpads (K162050). The performance data demonstrate that the device performs to specifications and is expected to be equivalent to the predicate devices cleared in K162050, in safety and effectiveness, for the specified use.