January 21, 2020

ZELTIQ Aesthetics, Inc.
Tammy Wharton
Senior Manager Regulatory Affairs
4410 Rosewood Drive
Pleasanton, California 94588

Re: K193566
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: December 20, 2019
Received: December 23, 2019

Dear Tammy Wharton:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193566

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, thigh, abdomen, and flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. In addition, the device is intended for cold-assisted lipolysis of the submental and submandibular areas in individuals with a BMI up to 46.2. The device is intended to affect the appearance of visible fat bulges in the upper arm, bra fat, back fat, banana roll, submental and submandibular areas, thigh, abdomen and flank. When used for cold-assisted lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area.

Cooling with the device may also be used to minimize pain and thermal injury during laser and dermatological treatment 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.
4410 Rosewood Drive
Pleasanton, CA 94588

CONTACT:
Tammy Wharton
Senior Regulatory Affairs Manager
ZELTIQ Aesthetics, Inc.
Phone: 571-758-2123

DATE PREPARED: January 17, 2020

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: ZELTIQ CoolSculpting System (K183514)

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 applicators and accessories such as gelpads, cycle cards and geltraps. The device treats at a target temperature down to -11° C with an accuracy of +/- 0.5° C. The device will automatically stop the treatment if the interface temperature goes past the target temperature by more than 1°C when treating below 5°C.

V: 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 upper arm, bra fat, back fat, banana roll, thigh, abdomen, and flank, or "love handles" in individuals with a Body Mass Index (BMI) of

30 or less. In addition, the device is intended for cold-assisted lipolysis of the submental and submandibular areas in individuals with a BMI up to 46.2. The device is intended to affect the appearance of visible fat bulges in the upper arm, bra fat, back fat, banana roll, submental and submandibular areas, thigh, abdomen and flank. When used for cold-assisted lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area.

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The technological characteristics and operating principal associated with the treatment remain unchanged from the predicate device. The applicator cup has been updated to provide a single assembled unit incorporating the contour, thus eliminating the need for the gasket. Consequently, the geltrap is repositioned to the top of the applicator, latches and contour interface are removed from the applicator housing. The applicator heating and cooling technology and method remain unchanged utilizing the same Thermoelectric Coolers (TECs) to achieve heating and cooling. The temperature feedback control mechanism remains the same and the device monitoring is through software monitoring.

Changes were made to the predicate's (K183514) system hardware and the software to allow one or two treatments to be performed simultaneously. The vacuum and chiller sub-systems were updated to facilitate a second applicator in simultaneous use.

The control unit has been updated with two umbilicals attaching the applicators to the control unit rather than one to allow dual applications at the same time. The software user interface has been enhanced to include explanatory text of the dual application preparation steps on the software touchscreen display. The User Manual has been updated to reflect the changes.

No new risks were identified related to the modifications and, no new mitigations are required.

VII. PERFORMANCE DATA:

Biocompatibility testing
No material changes have been made to patient contacting components of the device, thus additional biocompatibility testing is not applicable. The device is not a sterile device and sterilization validation is not required associated with this change.

Electrical safety and electromagnetic compatibility (EMC)
The device has undergone electrical and mechanical safety performance testing and electromagnetic compatibility testing as a result of the changes referenced. The system complies with IEC 60601-1 AMD.1.ED.3.0B(2012) and IEC 60601-1-2 (Fourth Edition, 2014).

Software Verification and Validation Testing
The CoolSculpting System uses updated software on the Windows 10 operating system, which is the same as the predicate device (K183514). The graphic user interface (GUI) is still a touchscreen LCD when compared to the predicate device. In the subject device software, the workflow allows for dual applicators to be applied simultaneously rather than a single applicator. As a result, the Control system software has been updated to include the functionality. The device has undergone verification and validation testing of the software changes referenced. Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Cybersecurity

Cybersecurity risk management for the device was performed as part of the overall risk management process for the medical device and follows the guidance in the FDA document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The network connections (USB and cellular data modem) were assessed as part of risk management and design measures were implemented to secure the device for both safety and cybersecurity.

Performance Testing
Performance testing demonstrated that the CoolSculpting system met all performance requirements. As required by the "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use", testing confirmed that the interface temperature has a steady state accuracy within +/- 0.5°C of the target value, that feedback and control of the cooling mechanism is active during treatment, and that there is a mechanism incorporated into the device to ensure the device does not exceed a safe cooling limit. Since the

CoolSculpting System now has two vacuum systems to accommodate dual applicators, bench testing was also performed to verify the accuracy and performance of the vacuum.

The treatment parameters of the subject device operate within the previously cleared treatment range. The bench testing reports demonstrate the performance of the applicator at the treatment parameters of -11 °C for 35 minutes for the C150. The overall workflow has been enhanced to allow dual applicators, but the same workflow steps apply for each applicator. The efficacy of the CoolSculpting System has not changed as a result.

The CoolSculpting System is provided with applicators that are placed on the patient for treatments. The applicator shapes and sizes vary to accommodate different fat. The subject device system is compatible with the C150 (150mm Curved) applicator which is updated from the CoolAdvantage applicators. The CoolAdvantage applicators were previously cleared in K162050.

The C150 applicator cup has been updated to provide a single assembled unit incorporating the contour, thus eliminating the need for the gasket. Consequently, the geltrap is repositioned to the top of the applicator, latches and contour interface are removed from the applicator housing. The updated applicator demonstrated substantial equivalence to the previously-cleared versions via design verification and validation testing though ZELTIQ's design control process.

The device has undergone performance benchtop testing and shipping validation testing as a result of the changes referenced. The performance standards as set forth in the "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use", have been met.

Clinical Study
No clinical testing was conducted.