November 5, 2021

Zeltiq Aesthetics, Inc.
Vicky Chai
Associate Director Regulatory Affairs
4410 Rosewood Drive
Pleasanton, California 94588

Re: K212707
Trade/Device Name: CoolSculpting Elite System
Regulation Number: 21 CFR 878.4340
Regulation Name: Contact cooling system for aesthetic use
Regulatory Class: Class II
Product Code: OOK
Dated: October 6, 2021
Received: October 8, 2021

Dear Vicky Chai:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212707

Device Name
CoolSculpting Elite System

Indications for Use *(Describe)*
The CoolSculpting Elite 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 Elite 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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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.
4410 Rosewood Drive
Pleasanton, CA 94588

CONTACT: Vicky Chai
Associate Director Regulatory Affairs
ZELTIQ Aesthetics, Inc.
Phone: (919)564-8811
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DATE PREPARED: September 29, 2021

II. DEVICE:

TRADE NAME: CoolSculpting Elite 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 (K193566)

IV. DEVICE DESCRIPTION:
The CoolSculpting Elite System is a portable thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The CoolSculpting Elite 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 -15°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 Elite 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 treatments and act as a local anesthetic for procedures that induce minor local discomfort.

The CoolSculpting Elite 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 principals associated with the treatment remain unchanged from the predicate device.

The sensitivity of the touchscreen of the system was improved over the predicate to allow users to actuate screen functions with their fingertips versus actuating the screen function with a full finger press.

Applicators with different dimensions have been introduced for compatible use with the CoolSculpting Elite System. The dimension and treatment profile of all newly introduced applicators are within the overarching range of the previously cleared applicators.

A standalone umbilical was introduced, which could be used for multiple applicators for the purpose of saving storage space in clinics.

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.

See Table 1 for the comparison between the subject device and the predicate device.

Table 1 Comparison between the subject device and the predicate device.

Characteristics	Predicate Device – K193566, ZELTIQ CoolSculpting System	Subject Device – K212707, CoolSculpting Elite System
System Components (Device Identification)	Control unit, umbilical hose, applicator	Control unit, umbilical hose, applicators, detachable umbilical
Compatible Applicators	C150	C150, C120, C240, C80, F125, F165, S150
Environment of Use	Healthcare facility	Same
Mechanism of Action	Non-invasive cooling applied to skin surface	Same
Cooling Method	Thermoelectric Coolers (TEC's)	Same
Energy Source	Alternating Current	Same
Device Monitor During Procedure	Software Monitoring	Same
Chiller	Two pumps	Same
Vacuum Pump	Two pumps	Same
Applicator Port on Control Unit	Two	Same
Key Performance	Temperature accuracy of system, including all applicators: ±0.5°C, Device doesn't exceed a safe cooling/vacuum limit.	Same
Temperature Feedback Control Mechanism	Closed loop software control of TEC power based primarily on skin interface temperature	Same
Software	Operating System: WIN 10 Computer: COM Express module or Quad core i7 processor User Interface: Touchscreen LCD	Same
Workflow	Customer attaches one or two applicator(s) to control unit with umbilical cords and follows the onscreen prompts to treat patients.	Same

VII. PERFORMANCE DATA:

Biocompatibility testing

No material changes have been made to patient contacting components of the device, thus additional biocompatibility testing is not indicated.

Electrical safety and electromagnetic compatibility (EMC)

The CoolSculpting Elite System 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 Elite System uses updated software on the Windows 10 operating system, which is the same as the predicate device (K193566). Changes were made to the predicate's (K193566) system software to allow for compatibility with the modified applicators, to improve the overall user experience, to offer cosmetic improvement on the Graphic User Interface, to facilitate remote software download and to address certain system defects that were identified in the field.

The CoolSculpting Elite System 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".

Changes were made to the predicate's (K193566) system software to allow for software download. 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 Elite 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/vacuum limit.

The treatment profiles of the subject device operate within the previously cleared treatment range. The bench testing reports demonstrate that the applicators perform as intended within the pre-set parameters of each treatment profile. . The treatment workflow has been modified to allow the connection between the applicator and the umbilical. The safety and efficacy of the CoolSculpting Elite System has not changed as a result.

The CoolSculpting Elite System is provided with applicators that are placed on the patient for treatments. The applicators vary in shape and size to accommodate different physical aspects of the treatment areas and the best fit for each patient. The subject device system is compatible with

- The C150 (150mm Curved vacuum) applicator is to be used with the standalone umbilical, which is a modification to the C150 (150mm Curved vacuum) applicator with connected umbilical as enclosed in the predicate's (K193566) system. The standalone detachable umbilical was offered to connect the applicator and the control unit;
- The C120 (120mm Curved vacuum) applicator, which is a dimension extension to the C150 applicator as enclosed in the predicate's (K193566) system and is updated from the CoolAdvantage Petite applicator with Core/Curve contour. The CoolAdvantage Petite applicator was previously cleared in K171069;
- The C240 (240mm Curved vacuum) applicator, which is a dimension extension to the C150 applicator as enclosed in the predicate's (K193566) system and is updated from the CoolAdvantage Plus applicator. The CoolAdvantage Plus applicator was previously cleared in K171069;
- The F125 (125mm Flat vacuum) applicator, which is a dimension extension to the C150 applicator as enclosed in the predicate's (K193566) system and is updated from the CoolAdvantage Petite applicator with Flat contour. The CoolAdvantage Petite applicator was previously cleared in K171069;
- The F165 (165mm Flat vacuum) applicator, which is a dimension extension to the C150 applicator as enclosed in the predicate's (K193566) system and is updated from the CoolAdvantage applicator with Fit contour. The CoolAdvantage applicator was previously cleared in K162050;
- The C80 (80mm Curved vacuum) applicator, which is a dimension extension to the C150 applicator as enclosed in the predicate's (K193566) system and is updated from the CoolMini applicator. The CoolMini applicator was previously cleared in K151179;
- The Surface (150mm Surface) applicator, which leverages the electrical design of the C150 applicator as enclosed in the predicate's (K193566) system and leverages the mechanical design of the CoolSmooth Pro applicator. The CoolSmooth Pro applicator was previously cleared in K151179.

The CoolSculpting Elite System has undergone performance bench testing, as well as design verification and validation 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.

Conclusion

Results of design verification and validation testing demonstrated substantial equivalence of the updated applicators to the previously cleared versions. Therefore, the subject device is as safe and effective as previously cleared predicate device for the proposed intended use.