August 29, 2018

ZELTIQ Aesthetics, Inc.
Mr. Alex Chang
Sr. Manager, Regulatory Affairs
4410 Rosewood Drive
Pleasanton, California 94588

Re: K181740
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: June 29, 2018
Received: July 2, 2018

Dear Mr. Chang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181740

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 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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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.

I.SUBMITTER: ZELTIQ™ Aesthetics, Inc.
4410 Rosewood Drive
Pleasanton, CA 94588

CONTACT: Alex Chang
Sr. Manager, Regulatory Affairs
ZELTIQ Aesthetics, Inc.
Phone: 925-621-7415

DATE PREPARED: June 29, 2018

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 DEVICES: **Predicate Device:** CoolSculpting System (K172144, OOK)

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.

V. INDICATIONS 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.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The ZELTIQ CoolSculpting System is the same as the device cleared in K172144. No changes have been made to the device to accommodate the indication of the submandibular area or clarification of BMI.

The CoolSculpting System has been established as safe and effective through many prior clearances (the most recent is K172144).

VII. PERFORMANCE DATA:

Biocompatibility testing

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K172144).

Electrical safety and electromagnetic compatibility (EMC)

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K172144).

Software Verification and Validation Testing

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K172144).

Performance testing

The ZELTIQ CoolSculpting System is the same as the previously cleared predicate device (K172144).

Clinical Performance Data:
Clinical publications demonstrated the safety and effectiveness of the CoolSculpting System for treatment of the submandibular area.

A review of published literature and clinical studies revealed 228 cryolipolysis treatment cycles during clinical studies of the submental and submandibular areas in a population with a BMI ranging from 22.8 to 46.2.

Effectiveness was measured by several techniques including ultrasound measurement, caliper measurement, Magnetic Resonance Imaging (MRI), three-dimensional (3D) quantification of volume reduction, patient satisfaction, and blinded, independent review of clinical photographs. The mean ultrasound measurement of fat layer reduction was 2.4 mm with a range from 2.0 to 2.8 mm. The mean caliper measurement of fat layer reduction was 3.17 mm (around 33%) with a range from 2.3 to 4.0 mm. The single study using MRI imaging showed mean reduction of 1.78 mm or 17% subcutaneous fat layer reduction. The 3D imaging showed a mean calculated reduction of 8.5 mL fat volume, and calculated reduction in submental laxity by 2.25 mm (Li, DaSilva, Canfield, & McDaniel, Use of 3-Dimensional Imaging in Submental Fat Reduction After Cryolipolysis, 2018). Three-dimensional volumetric measurement showed a fat reduction of 4.82 cm^3 (Bernstein & Bloom, 2017). Blinded, independent photo review was conducted in several studies with correct identification of baseline photographs ranging from 60% to 91% averaging 77%. Patient satisfaction ranged from 80% to 93% averaging 85%.

There were no procedure or device related serious adverse events reported. Common procedural side effects were transient and resolved without long term effect. The clinical study literature indicates that cryolipolysis is a safe and effective non-surgical procedure for subcutaneous fat reduction in the submental and submandibular areas. Clinical literature review and post-market data have demonstrated the same low-risk safety profile. The published data provided in this submission clearly demonstrate the safety and effectiveness profile of the CoolSculpting System for the indication of treatment of the submandibular and submental areas in a population with a BMI ranging from 22.8 to 46.2.

VIII. CONCLUSION:

The ZELTIQ CoolSculpting System is the same as the device cleared in K172144. No changes have been made to the device to accommodate this indication of cold-assisted lipolysis in the submandibular area and clarification of BMI in this patient population.

The CoolSculpting System is substantially equivalent to the predicate device for this new indication for use. The clinical data shows results from cryolipolysis in the submandibular area meeting both the safety and effectiveness endpoints.

The CoolSculpting System has been established as safe and effective through many prior clearances (the most recent is K172144).

The CoolSculpting System has not been changed to accommodate this expanded indication for treatment of the submandibular area and increased BMI for submental and submandibular patients. The

clinical data indicates the same safety and effectiveness for the CoolSculpting System for this expanded indications for use for the submandibular area and increased BMI for submental and submandibular treatments. As such, the CoolSculpting System is substantially equivalent to the predicate device (previously cleared CoolSculpting System, K172144).