September 12, 2024

ZELTIQ Aesthetics, Inc.(acquired by Allergan Aesthetics and now, an AbbVie, Inc. company)
Victoria Montemayor
Manager, Regulatory Affairs
4410 Rosewood Drive
Pleasanton, California 94588

Re: K233732
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: August 16, 2024
Received: August 16, 2024

Dear Victoria Montemayor:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.09.12 15:18:34 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233732

Device Name

CoolSculpting Elite System (N/A)

Indications for Use *(Describe)*

The CoolSculpting Elite System is a skin cooling or heating device. It can be used in cooling or heating mode.

Cooling Mode
• 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.
• Intended for cold-assisted lipolysis of the submental and submandibular areas in individuals with a BMI up to 46.2.
• 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.
• Can be used to minimize pain and thermal injury during laser and dermatological treatments.
• Can be used as a local anesthetic for procedures that induce minor local discomfort.

Heating or Cooling Mode
• Can be used to minimize pain post-trauma and post-surgery.
• Can be used to provide temporary relief of minor aches, pains, and muscle spasms.
• The ZELTIQ Pretreatment Skin Wipe and gel pad 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.

510(K) SUMMARY

I. SUBMITTER

510(k) Submitter:	ZELTIQ Aesthetics, Inc. 4410 Rosewood Drive Pleasanton, CA 94588 USA	
Contact Person(s):	**Primary Contact** Victoria Montemayor Manager, Regulatory Affairs Phone: (949) 761-0747 Email: victoria.montemayor@abbvie.com	**Secondary Contact** Bryan McMahon Director, Global Regulatory Affairs Phone: (720) 425-5661 Email: bryan.mcmahon@abbvie.com
Date Prepared:	April 30, 2024	

II. DEVICE

Device Trade Name:	CoolSculpting Elite System
Medical Specialty	General and Plastic Surgery
Regulation	21 CFR 878.4340 Class II Special Control, Contact Cooling System for Aesthetic Use
Regulatory Class	Class II
Product Code	OOK Dermal Cooling Pack/Vacuum/Massager

III. PREDICATE DEVICE

Predicate Device	CoolSculpting Elite System K212707 (cleared on November 5, 2021)

IV. DEVICE DESCRIPTION

The CoolSculpting Elite System is a portable thermoelectric cooling device that applies controlled cooling to a treatment site. The CoolSculpting Elite System comprises of a control unit, detachable applicators, and accessories such as cycle cards, CoolAdhesive gelpads, gel traps, pretreatment skin wipes, liners, foam borders, and comfort straps. The device treats 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.

510(K) SUMMARY

V. INDICATIONS FOR USE

The CoolSculpting Elite System is a skin cooling or heating device. It can be used in cooling or heating mode. A list of indications for use is provided below.

Mode	Indications
Cooling	• 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. • Intended for cold-assisted lipolysis of the submental and submandibular areas in individuals with a BMI up to 46.2. • 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. • Can be used to minimize pain and thermal injury during laser and dermatological treatments. • Can be used as a local anesthetic for procedures that induce minor local discomfort.
Heating or cooling	• Can be used to minimize pain-trauma and post-surgery. • Can be used to provide temporary relief of minor aches, pains, and muscle spasms. • The ZELTIQ Pretreatment Skin Wipe and gel pad facilitate thermal contact of the device with a patient’s skin by mitigating minor variances in device-to-skin contact.

510(K) SUMMARY

VI. COMPARISON TO PREDICATE DEVICE

The purpose of this Traditional 510(k) submission is to introduce a software update, which notably includes Wi-Fi functionality, and new surface applicator, S180. The modified CoolSculpting Elite System is identical to the predicate device in terms of principle of operation, mechanical and electrical features, performance specifications, software, hardware, algorithm, and treatment workflow. There are minor differences to the indications for use and user interface.

The addition of Wi-Fi to the subject device is intended to allow data transfer between the device and cloud; the data consists of logs for usage monitoring, errors trending, engineering diagnostics, and debugging as well as patch deployment and remains unchanged; the Wi-Fi functionality is not used to achieve the device's intended use. The addition of the S180 applicator is intended to expand options when selecting an appropriate treatment plan for patients; the treatment sites targeted by the surface applicator and overall design remain unchanged.

The differences between the modified CoolSculpting Elite System and predicate device do not raise new questions of safety and effectiveness, and these devices are substantially equivalent based on the criteria described in 21 CFR §807.100.

V. PERFORMANCE TESTING

Non-clinical testing was successfully completed to demonstrate that the CoolSculpting Elite System, with the software update and new S180 applicator, is equivalent to the predicate device. Testing results confirmed that the modified CoolSculpting Elite System functions as intended, and no new issues of safety and effectiveness were identified.

VI. SOFTWARE AND CYBERSECURITY

An evaluation of the CoolSculpting Elite System's software (including hardware and firmware) documentation was performed for cybersecurity considerations. The evaluation results demonstrated that the CoolSculpting Elite System complies with the requirements set forth in Section 524B, *Ensuring Cybersecurity of Medical Devices*, of the FD&C Act.

VII. CONCLUSION

The information presented in this Traditional Premarket Notification demonstrates that the modified CoolSculpting Elite System is substantially equivalent to the predicate device and will perform as safely and effectively within the intended use.