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.

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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 (K181740)

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 applicators and accessories such as gelpads, cycle cards, geltraps, and gaskets.

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.

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 technological characteristics and operating principal associated with the treatment remain unchanged from the predicate device. The size and shape of the applicators remain the same. 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 (K181740) system hardware and the software to create the next generation of the CoolSculpting System. The chiller has been changed from a TEC based chiller to a refrigerator-based model. The single board computer and the software operating system were updated to current technology. The size and shape of the control unit have changed to give it a more modern look and feel, and the user interface has been enhanced to include more explanatory text of the preparation steps on the new software touchscreen display.

VII. PERFORMANCE DATA:

Biocompatibility testing

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

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 (Third Edition, 2005) and IEC 60601-1-2 (Fourth Edition, 2014).

Software Verification and Validation Testing

The CoolSculpting System uses a new operating system and new software architecture. The operating system used in the predicate device (K181740) is Windows CE and has been changed to a Windows 10 operating system. The graphic user interface (GUI) is still a touchscreen LCD as in the predicate device. One step in the treatment instructions has changed in respect to the gelpad application, but the overall workflow has not changed. The device has undergone verification and validation testing as a result 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.

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 has a vacuum system, bench testing was also performed to verify the accuracy and performance of the vacuum.

The following applicators are to be used with the CoolSculpting system: The CoolAdvantage applicator and the CoolAdvantage Petite applicator. The CoolAdvantage and CoolAdvantage Petite were previously cleared in K162050 and K171069, respectively. These two applicators have been modified to accommodate the updated control unit. Version 2 of the CoolAdvantage and CoolAdvantage Petite applicators have been demonstrated substantial equivalence to the previously-cleared versions via design verification and validation testing though ZELTIQ's design control process. The treatment parameters of the subject device operate within the cleared treatment range. The bench testing reports demonstrate the performance of these applicators at the treatment parameters of -11 °C for 35 minutes. The overall workflow or efficacy of the CoolSculpting System has not changed as a result.

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.

VIII. CONCLUSION:

The Indication for Use for the ZELTIQ CoolSculpting System is the same as the device cleared in K181740. The changes that have been made to the system's hardware and software do not affect the intended use or risk profile of the device. The subject device still utilizes all the same main components as the predicate device.