June 6, 2018

Cutera, Inc.
Raymond Lee
Vice President, Regulatory Affairs and Quality Assurance
3240 Bayshore Blvd.
Brisbane, California 94005

Re: K180709
Trade/Device Name: truSculpt RF Device; truSculpt; truSculpt 3D
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: March 16, 2018
Received: March 19, 2018

Dear Raymond Lee:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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)*
K180709

Device Name(s)
truSculpt RF Device; truSculpt; truSculpt 3D

Indications for Use *(Describe)*

The truSculpt RF energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions, such as relief of pain and muscle spasms and increase in local circulation.

Additionally, the 2 MHz setting for the 40 cm^2 handpiece is indicated for reduction in circumference of the abdomen and non-invasive lipolysis (breakdown of fat) of the abdomen.

The truSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite.

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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Section 5
510(k) Summary

This 510(k) Summary of safety and effectiveness for the truSculpt RF Device is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Applicant:	Cutera, Inc.
Address:	3240 Bayshore Blvd. Brisbane, CA 94005
Contact Person:	Raymond Lee
Telephone: Fax: Email:	415-657-5539 415-715-3539 rlee@cutera.com
Preparation Date:	March 16, 2018
Device Trade Names:	truSculpt RF Device; truSculpt; truSculpt 3D
Common Name:	Massager, Vacuum, Radio Frequency Induced Heat
Classification Name:	Electrosurgical cutting and coagulation device and accessories PBX, GEI, 21 CFR 878.4400
Legally Marketed Predicate Devices:	truSculpt RF Device (K162512) Syneron SlimShape System (K163415)
Intended Use:	The truSculpt RF Device is intended to generate heat within body tissues for the treatment of selected medical conditions, such as the relief of minor aches, pain, and muscle spasms; an increase in local circulation; a reduction in circumference of the abdomen; and non-invasive lipolysis (breakdown of fat) of the abdomen. The truGlide roller is intended to provide temporary reduction in the appearance of cellulite.
Indications for Use:	The truSculpt RF energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions, such as relief of pain and muscle spasms and increase in local circulation. Additionally, the 2 MHz setting for the 40 cm^2 handpiece is indicated for reduction in circumference of the abdomen and non-invasive lipolysis (breakdown of fat) of the abdomen. The truSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite.
Device Description:	The truSculpt RF Device consists of a console, one or more RF handpieces that connect to the console with an umbilical cable, and a truGlide massage roller. All system functions are controlled through the console. The handpieces deliver RF energy to generate a heating profile that produces a moderate temperature rise in the subcutaneous tissue, while monitoring epidermal temperature. The truGlide is a separate mechanical roller that can be used as a massager.

Attachment 5
510(K) Summary

Summary of Technological Characteristics:

The truSculpt RF Device that is the subject of this submission has identical technological characteristics as the previously cleared truSculpt RF Device and very similar technological characteristics as the Syneron SlimShape System. All three devices are comprised of a console and RF applicator(s). The consoles for all devices consist of a mechanical enclosure, an RF generator, control electronics, a touch-screen user interface, and a control microprocessor. Although the truSculpt RF Device no longer includes an optional vacuum feature (removed in K133739), this difference does not alter the therapeutic effect for the intended use of the device, nor does it raise new types of safety or effectiveness questions, as demonstrated by the clinical study results.

The shape and dimensions of the RF applicators of the truSculpt RF Device that is the subject of this submission are identical to those of the previously cleared truSculpt RF Device. Differences in the shape and dimensions of the RF applicators of the truSculpt RF Device and the Syneron SlimShape System do not raise any new or different safety or effectiveness questions, since the device RF applicators have the same or similar energy parameters, are intended for use in the same or similar treatment areas, and are intended for use on the same or similar population.

The truSculpt RF Device that is the subject of this submission heats tissue through delivery of RF energy at 1 MHz and 2 MHz, which is identical to the previously cleared truSculpt RF Device. The Syneron SlimShape System also heats tissue through delivery of RF energy at 1 MHz but does not have a 2 MHz option. All three devices use temperature control mechanisms with redundant temperature sensors in the RF applicators to dynamically adjust the RF power delivered to first reach and then maintain therapeutic temperatures to achieve equivalent therapeutic effects, as demonstrated by the clinical study results. The clinical study results confirm that any technological differences between the truSculpt RF Device that is the subject of this submission and its predicates do not raise new types of safety or effectiveness questions.

Performance Data:

IEC 60601-1 Medical Electrical Equipment – Part 1:
General Requirements for Safety (Edition 3.0, 2005 + AMD1:2012) including:

- IEC 60601-2-2 Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories – Test Report Attachment 5

IEC 60601-1-2 Medical Electrical Equipment – Part 1-2:
General Requirements for Safety – Collateral Standard: Electromagnetic Disturbances (Edition 3, 2007)

Software Verification and Validation Testing Report: truSculpt 3D

V0005 rT-Addendum, truSculpt SW Release
This document describes the specific tests that were used to verify and validate the software used in the truSculpt 3D. Testing included verification of correct Startup/Flash screens, Operating screens and

screen selection; Software Version confirmation; Checksum verification; clearing of log files; frequency verification for all handpieces and operating modes; correct function of displays and indicators; correct function of controls, buttons, and inputs; temperature limits; treatment countdown indicator; calibrated delivery; screen data accuracy; date and time entry; data pop-up screens; error conditions; induced fault conditions; shot and error log capture and printing; and anomalies, if any, encountered during testing. No anomalies were encountered during testing.

Results of Clinical Studies:

Two prospective IRB-approved clinical studies were conducted with the truSculpt RF Device on the intended population to gather clinical data needed to support the revised indications for use.

Non-invasive Lipolysis Study, C-17-TS13

C-17-TS13 was a single-center, prospective, non-randomized, open-label study conducted to evaluate the safety and efficacy of treatment with the Cutera truSculpt RF Device for non-invasive lipolysis in the abdominal region.

Twelve subjects, including Caucasian, Asian and African females (92%) and males (8%), aged 24-58 years (median age: 42), with Fitzpatrick skin types II-VI, who were scheduled to undergo an abdominoplasty surgery were enrolled and received one treatment with the truSculpt RF Device on one abdominal subarea, with the contralateral side abdominal subarea being left untreated to serve as a control. Subjects were assigned to 6 subgroups based upon the timing of their abdominoplasty surgery with respect to the RF treatment date. Up to 2 subjects were enrolled into each subgroup: D0, D10, D20, D30, D60 and D90, where the number refers to the days between RF treatment and the scheduled abdominoplasty surgery date. Biopsies were harvested from the treatment and control abdominal subareas during the abdominoplasty surgery. These biopsies were cultured, stained and examined by a board-certified dermatopathologist leading to the findings summarized below.

Epidermal and dermal tissues were unaffected by RF treatment and were equivalent and indistinguishable in all subject biopsies.

Biopsies from the control areas showed normal subcutaneous adipose tissue structures in all biopsies with no indication of changes from the contralateral RF treatment area.

In contrast, biopsies from the truSculpt RF treatment abdominal areas showed adipocyte necrosis and/or inflammatory immune cell response to the subcutaneous fat. Necrosis was observed immediately and out to sixty days following treatment for six subjects. Necrosis was not present for five subjects, but four of the five subjects not showing necrosis did present inflammatory immune cell response spanning zero to ninety days following treatment. One subject at ten days post treatment did not show any response to treatment.

Acute inflammation was present immediately and out to 20 days following treatment. Peak adipocyte death and fat necrosis was observed 30 days post treatment with approximately 33% of adipocytes affected from just beneath

the dermis up to approximately 1.5 cm beneath the skin surface with no damage seen at the base of the tissue sample (3 cm). Sixty days following treatment, fat necrosis is still present although confined to small, focal areas with less than 20% of the subcutaneous affected. At the final ninety day time point, there was minimal inflammation comprised of few lymphocytes and neutrophils.

All subjects experienced transient mild to moderate erythema and edema post treatment. For eleven subjects, the mild to moderate erythema and edema resolved in 1-4 hours. One subject reported moderate erythema, mild edema and mild post-treatment pain, which persisted for 1 day.

The study results demonstrate that RF treatment with the truSculpt RF Device consistently leads to discrete areas of fat necrosis within the subcutaneous tissue. The effect is present solely in the subcutaneous tissue, while the dermal and epidermal layers remain unaffected by treatment.

The study design and results are summarized in the table below.

Study Design	A single-center, prospective, non-randomized, open-label study
Sample Size	12 subjects enrolled
Main Criteria for Inclusion	Male or Female, 24 to 58 years of age (inclusive); Fitzpatrick Skin Type I – VI; who are scheduled for abdominoplasty and willing to provide histology samples during the surgery from the intended to be harvested areas; has visible fat bulges on the abdomen and palpable fat pockets superior to iliac crest located bilaterally in the lower back flank region; has a Body Mass Index (BMI) ≥ 20 and ≤ 30
Follow-up Intervals	1 follow-up on the day of planned abdominoplasty

Endpoints	**Efficacy** Histological evaluation of tissue for selective fat necrosis, with sparing of the dermis and epidermis, following truSculpt treatment vs. untreated contralateral control **Safety** Incidence and severity of adverse device effects during the study period, including subject pain level during RF treatment
Summary Results	**Efficacy** Met endpoints. Epidermal and dermal tissues were unaffected by RF treatment and were equivalent and indistinguishable in all subject biopsies. Biopsies from the control areas showed normal subcutaneous adipose tissue structures in all biopsies with no indication of changes from the contralateral RF treatment area. **Safety** No adverse events were observed. The immediate responses included mild to moderate erythema and edema, which resolved with no intervention.

Long-term Follow-up Circumferential Reduction Study, C-17-TS15

C-17-TS15 was a single-center, observational, prospective study of subjects, aged 24-60 years at the time of RF treatment, who completed participation in the Treatment Group of Protocol C-16-TS11 “Pivotal Study of the truSculpt Radiofrequency Device for Circumferential Reduction” (46 subjects in total; and the maximum potential enrollment for this study) for sustained long-term circumferential reduction.

Data from protocol C-16-TS11 comparing subject outcomes from the treatment and sham treatment study arms were previously submitted under K162512, resulting in FDA clearance of a new indication for use for the truSculpt RF Device: “temporary reduction in circumference of the abdomen”.

All potential subjects were contacted in no fewer than five attempts by phone calls, emails, and/or texts and were invited to participate in a new study involving one study visit: 18 months ± 2 months following their original treatment under study Protocol C-16-TS11. Of the forty-six potential subjects: two were not able to be contacted; four were not interested in participating; six were unable to participate because of relocation, travel or work constraints; nine were excluded as they had elected to have additional truSculpt RF treatments of the abdomen and flanks for further circumferential reduction after being released from study C-16-TS11 restrictions; three were excluded for various exclusion criteria (pregnancy, medical condition, and abdominal surgery, respectively); and the remaining twenty-two subjects were scheduled for screening visits. Of the twenty-two subjects screened, seven had weight changes beyond ± 5% of baseline weight and were therefore deemed to have not met an inclusion criterion and excused prior to enrollment. The remaining fifteen subjects (32.6% of potential subjects) were enrolled.

The circumferential measurements recorded during the 18-month follow-up visit for the 15 subjects enrolled in C-17-TS15, when compared with the subjects' baseline circumferential measurements recorded and reported in C-16-TS11, demonstrated a statistical-significant, sustained reduction in the circumference of the abdomen of 2.30 ± 0.51 cm (SEM; $p < 0.001$).

No treatment-related adverse effects were observed or reported developing after the 12-week follow-up visit of C-16-TS11, at which point all treatment-related expected side effects had resolved without medical intervention.

The study design and results are summarized in the table below.

Study Design	a single-center, observational, prospective study
Sample Size	46 subjects in total; 15 subjects enrolled for long-term circumferential reduction
Main Criteria for Inclusion	Completed participation in the Treatment Group of Protocol C-16-TS11; and maintained the same weight within ± 5% of the baseline
Follow-up Intervals	18 months post treatment in C-16-TS11
Endpoints	**Efficacy** Difference in circumferential measurement at the 18-month follow-up visit when compared with the baseline and 12-week follow-up visits, as measured and reported in C-16-TS11 (K162512).

	Safety Incidence and severity of treatment-related adverse effects developing after the final 12-week follow-up visit of C-16-TS11.
Summary Results	**Efficacy** The difference between the circumferential measurements recorded during the 18-month follow-up visit when compared with the subjects' baseline circumferential measurements showed sustained reduction in the circumference of the abdomen of 2.30 ± 0.51 cm . The 18-month circumferential-measurement data when compared with the 12-week circumferential-measurement data showed a 0.17 ± 0.49 cm increase in circumference of the abdomen for this cohort of 15 subjects (p = 0.36). **Safety** No treatment-related adverse effects were observed or reported developing after the 12-week follow-up visit of C-16-TS11, at which point in time all treatment-related expected side effects had resolved without medical intervention.

Conclusion:

The truSculpt RF Device that is the subject of this submission has identical technological characteristics and principles of operation as the previously cleared truSculpt RF Device and very similar technological characteristics and principles of operation as the Syneron SlimShape System.

Performance data and clinical study results demonstrate that any differences between the truSculpt RF Device and its predicate devices do not raise new types of safety or effectiveness questions.

Clinical studies conducted with the truSculpt RF Device that is the subject of this submission have demonstrated the safety and effectiveness profile of the device in the intended population for the requested indications for use held by the Syneron SlimShape System.

The truSculpt RF Device is substantially equivalent to the predicate devices.

Table 5A—Technical Specification Comparison

	Cutera truSculpt RF Device (current submission)	**Cutera truSculpt RF Device (K162512)**	**Syneron SlimShape System (K163415)**
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency + Infrared
Massage	Yes	Yes	Yes
Vacuum (suction)	No	No	Yes
Temperature sensing	Yes	Yes	Yes
Temperature sensing active control	Yes	Yes	Yes
Treatment activation	Fingerswitch	Fingerswitch	Control Screen Button
Area treated	16 cm^2 and 40 cm^2	16 cm^2 and 40 cm^2	Unknown
Electrode shape	Square or Rectangle	Square or Rectangle	Rectangle
RF frequency	1 MHz and 2 MHz	1 MHz and 2 MHZ	1 MHz
RF type	Bipolar / Monopolar	Bipolar / Monopolar	Bipolar
Max RF power	300 W	300 W	Unknown
Patient contact material	Polyethylene (3M Tegaderm) and 316 SS	Polyethylene (3M Tegaderm) and 316 SS	Unknown