



Food and Drug Administration
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December 9, 2016

Cutera, Inc.
Bradley Renton, Ph.D.
Vice President, Regulatory and Medical Affairs, & Compliance Officer
3240 Bayshore Blvd.
Brisbane, California 94005

Re: K162512

Trade/Device Name: TruSculpt
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: September 7, 2016
Received: September 8, 2016

Dear Dr. Renton:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Jennifer R.
Stevenson -A**

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

Indications for Use

510(k) Number (if known)

K162512

Device Name

truSculpt

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 cm² handpiece is indicated for temporary reduction in circumference 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

K162512

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.

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Contact Person: Bradley Renton

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Preparation Date: December 6, 2016

Device Trade Name: truSculpt

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: Cutera truSculpt RF Device (K133739)
BTL XP1000 RF (K143559)
Syneron Transcend (K120510)

Device Description: The truSculpt 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. In addition, there is a separate mechanical roller that can be used as a massager.

Intended Use: The truSculpt 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; and temporary reduction in circumference of the abdomen. It is also 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 cm² handpiece is indicated for temporary reduction in circumference of the abdomen.

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

Non Clinical
Performance Data:

The truSculpt was successfully tested to the following standards in entirety and there were no exceptions:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (Edition 3.0, 2005 + CORR. 1:2006 + CORR. 2:2007)

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

truSculpt Software Verification and Validation Testing Report:

This document describes the specific tests that were used to verify and validate the software used in the truSculpt system. 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.

Substantial
Equivalence
Comparison:

The truSculpt RF device that is the subject of this submission has the same indications for use as the previously cleared truSculpt RF device, with the exception of the addition of a new indication for use that is identical to the cleared indication for use for the BTL XP1000 RF and Syneron Transcend.

For the requested indication for use, the subject device uses radiofrequency energy, which is the same energy type used by the BTL XP1000 RF, and Syneron Transcend; uses temperature sensing, which is the same as the BTL XP1000 RF and Syneron Transcend; treats an area of 40 cm², which is in between the areas treated for the BTL XP1000 RF (201 cm²) and the Syneron Transcend (1.3, 7.5, and 12.5 cm²); and uses a RF frequency of 2 MHz, which is between the 1 MHz operating frequency of the Syneron Transcend and the 27.12 MHz operating frequency of the BTL XP1000 RF. See Table 5A – Technical Specification Comparison below.

To ensure the technology differences between the subject device and the predicate devices for the same indication for use did not raise any new questions of safety or efficacy a clinical trial was conducted.

Clinical Performance
Data:

An IRB-approved single-center, controlled, randomized, pivotal study was conducted to evaluate the safety and efficacy of treatment with the Cutera truSculpt RF device for circumferential reduction in the abdominal and flank regions using the 2 MHz frequency. Seventy subjects were enrolled and treated in this study, with 47 subjects in the

Attachment 5 510(K) Summary

Treatment group and 23 subjects in the Sham group. Sixty-nine subjects completed the study with 1 subject lost to follow-up from the treatment group. Subjects received 1 treatment with the Cutera truSculpt RF device. Subjects were followed at 4 and 12 weeks post-treatment.

Standardized photographs were taken at baseline and at 4 and 12 weeks post-treatment. Efficacy was assessed through measurement of circumference at baseline and at 4 and 12 weeks post-treatment, as well as through subject assessment of improvement and satisfaction. Safety was evaluated through assessment of the incidence and severity of adverse effects, including subject pain level at the follow-ups.

At 12 weeks post-treatment, subjects in the Treatment group demonstrated an average circumferential reduction of 1.9 ± 0.1 cm. Subjects in the Sham group demonstrated an average circumferential reduction of 0 ± 0.1 cm. The difference in circumferential reduction between the Treatment and the Sham groups was 1.9 cm and was found to be statistically significant ($p < 0.0001$). Thirty-five (76%) subjects in the Treatment group were considered treatment responders (demonstrating 1 cm or greater reduction in circumferential reduction) at the 12-week follow-up visit. Four (17%) subjects in the Sham group were considered treatment responders (demonstrating 1 cm or greater reduction in circumferential reduction) at the 12-week follow-up visit. The difference in responder rates between the Treatment and Sham groups was also found to be statistically significant ($p < 0.0001$).

All subjects tolerated treatment with no treatments needing to be discontinued due to patient discomfort. The median pain score for the Treatment group was 6 on a 0 – 10 scale, with a range of pain scores from 4 – 8. As expected, all Treatment group subjects experienced erythema (redness) and edema (swelling), and 9 (20%) subjects experienced palpable lumps. Additionally, soreness was observed in 40 (87%) Treatment group subjects. All adverse effects resolved without intervention. No serious adverse events were noted.

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

Study Design	Prospective, randomized, controlled, single-center study
Sample Size	70 subjects enrolled (47 in Treatment group and 23 in Sham group)
Main Criteria for Inclusion	Male or female, 24 to 60 years of age (inclusive); Fitzpatrick Skin Type I – VI; 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	4 and 12 weeks post-treatment

<p>Endpoints</p>	<p>Primary Difference in circumferential measurement related to Sham and Treatment groups at 12 weeks post-treatment</p> <p>Secondary</p> <ul style="list-style-type: none"> • Subject assessment of improvement at 12 weeks post-treatment • Subject satisfaction level at 12 weeks post-treatment • Subject discomfort and pain levels during treatment <p>Safety Incidence and severity of adverse device effects during the study period, including subject pain level at follow-up visits</p>
<p>Summary Results</p>	<p>Efficacy</p> <ul style="list-style-type: none"> • Subjects in the Treatment group demonstrated a statistically significant reduction in circumference of 1.9 cm (Fisher’s exact test, two-tailed, $p < 0.0001$) of the treated flanks and abdomen, as compared to the Sham group, at 12 weeks following treatments. • Subjects in the Treatment group were satisfied (54%) and highly satisfied (30%) with their treatment outcome, and improvement was reported by 98% subjects. • No treatments were discontinued due to patient discomfort. The median pain score for the Treatment group was 6 on a 0 – 10 scale, with a range of pain scores from 4 – 8. <p>Safety As expected, all Treatment group subjects experienced erythema (redness) and edema (swelling), and 9 (20%) subjects experienced palpable lumps. Additionally, soreness was observed in 40 (87%) subjects. All adverse effects resolved without intervention. No serious adverse events noted.</p>

In conclusion, treatment using the Cutera truSculpt RF device was found to be safe and effective for temporary circumferential reduction, with no serious adverse effects.

Conclusion:

Cutera believes that the truSculpt RF device is substantially equivalent to the predicate devices for the requested indication for use and, based on the clinical data presented, any technical differences do not raise new questions of safety or effectiveness.

Table 5A – Technical Specification Comparison

	Cutera truSculpt RF Device (current submission)	Cutera truSculpt RF Device (K133739)	BTL XP1000 RF (K143559)	Syneron Transcend (K120510)
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency	Radiofrequency + Infrared
Massage	Yes	Yes	No	Yes
Vacuum (suction)	No	No	No	Yes
Temperature sensing	Yes	Yes	Yes	Yes
Temperature sensing active control	Yes	Yes	Yes	Yes
Treatment activation	Fingerswitch	Fingerswitch	Fingerswitch	Fingerswitch
Area treated	16, 25, and 40 cm ²	16 – 40 cm ²	201 cm ²	1.3, 7.5, and 12.5 cm ²
Electrode shape	Square or Rectangle	Square or Rectangle	Rectangle	Rectangle
RF frequency	1 MHz and 2 MHz	300 KHz – 50 MHz	27.12 MHz (±400 kHz)	1 MHz
RF type	Bipolar / Monopolar	Bipolar / Monopolar	Bipolar	Bipolar
Max RF power	300 W	300 W	200 W	150 W
Patient contact material	Polyethylene (3M Tegaderm) and 316 SS	Polyethylene (3M Tegaderm) and 316 SS	Unknown	Unknown