



Food and Drug Administration
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September 5, 2014

Cutera Incorporated
Dr. Bradley Renton
Vice President of Regulatory and Medical Affairs
3240 Bayshore Boulevard
Brisbane, California 94005

Re: K133739

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

Dated: June 6, 2014

Received: June 9, 2014

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" (21CFR 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 yours,

David Krause -S

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

Section 4
Indications for Use

K133739

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510(k) Number (if known): K133739

Device Name: truSculpt

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, muscle spasms, and increase in local circulation.

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

Prescription Use xx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5
510(K) Summary

K133739

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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: June 6, 2014

Device Trade Name: truSculpt

Common Name: Massager, Vacuum, Radio Frequency Induced Heat

Classification Name: Electrosurgical cutting and coagulation device and accessories, PBX, 21 CFR 878-4400

Legally Marketed Predicate Device: Cutera truSculpt RF Device (K122389)

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 and pain, muscle spasms, and an increase in local circulation. It is also intended to provide temporary reduction in the appearance of cellulite.

Specific Indications: 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, muscle spasms, and increase in local circulation.

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

Performance Data: IEC 60601-1 Medical Electrical Equipment – Part 1: General

Requirements for Safety

IEC 60601-1-2 Medical Electrical Equipment – Part 1-2:
General Requirements for Safety – Collateral Standard:
Electromagnetic Compatibility

truSculpt Software Verification and Validation Testing
Report (V0005 rN)

Results of Clinical Study: None

Summary of Technological Characteristics: See table below

Conclusion: Cutera believes that the requested changes are substantially equivalent to the predicate device and do not raise any new issues of safety or effectiveness.

Feature/Parameter	Current	Cutera truSculpt RF Device (K122389)
Infrared light	No	Yes (optional); up to 20 W max, 700 – 2000 nm
Massage	Yes – as a separate handpiece	Yes – as a separate handpiece
Vacuum (suction)	No	Yes
Temperature sensing	Yes	Yes
Temperature sensing active control	Yes	Yes
Treatment activation	Fingerswitch	Footswitch
Area treated	16 – 40 cm ²	16 – 40 cm ²
Electrode shape	Square or Rectangle	Square
RF frequency	300kHz – 50 MHz	300kHz – 50 MHz
RF type	Bipolar / Monopolar	Bipolar / Monopolar
Max RF power	300 W	300 W
Duty cycle	0 – 100%	0 – 100%
Patient contact material	Polyethylene (3M Tegaderm) and 316 SS	Polyethylene (3M Tegaderm) and 316 SS