DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 2, 2017

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

Re: K172004
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: June 30, 2017
Received: July 3, 2017

Dear Mr. 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 -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172004

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	Bradley Renton
Telephone: Fax: Email:	415-657-5568 – phone 415-715-3568 – fax brenton@cutera.com
Preparation Date:	August 1, 2017
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 (K162512) Syneron SlimShape System (K163415)
Legally Marketed Reference Devices:	Cynosure SculpSure (K160470)
Device Description:	The modified truSculpt RF device consists of a console; one 16 cm^2 RF handpiece; up to six 40 cm^2 puck-style RF handpieces that can attach to belts configured for hands-free abdominal and flank treatments for circumferential reduction; adjustable patient belts; a patient comfort switch; 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 cm^2 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.

Device Modifications:

In the modified device, the RF output is directed through a multiplexor to power up to six treatment handpieces in sequence. The modification also adds a patient-activated treatment termination switch; belts configured to enable up to six 40 cm^2 treatment handpieces to be positioned on the patient's abdomen and flanks prior to treatment for circumferential reduction; and a minor form factor change to the 40 cm^2 handpiece to enable it to attach to the patient belts. There are no changes to the indications for use.

When performing abdominal circumferential reduction treatments using the belts to position the form-factor modified 40 cm^2 handpieces, the identical treatment parameters are available for selection as used in the clinical trial to gain this indication for use, including area treated and RF dose (time and temperature).

Cutera has determined that no new risks have been introduced due to the above changes, as activating multiple handpieces in sequence is equivalent to the operator sequentially moving a single handpiece to a new location and then beginning a new treatment application; and patient feedback was used in the unmodified truSculpt to determine tolerable settings.

Performance Data:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (Edition 3.1, 2012), including:

- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety - Collateral Standard: Usability (Edition 3.1, 2013) – Test Report Attachment 4
- 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

The product also fulfills the requirements of AAMI/ANSI ES60601-1:2005+A2 (R2012) + A1.

IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Disturbances (Edition 4.0, 2014)

A patient comfort switch was added to mitigate risks during hands-free treatment with the modified truSculpt device. The function of the comfort switch is defined in the Software Requirements Specification (SRS) for the modified device. The performance of the patient comfort switch within the modified truSculpt device was verified and validated during software V&V testing. All tests were passed. There were no exceptions.

A multiplexor board was designed and added to the truSculpt console to direct RF output to any of 6 output ports to which RF handpieces can be attached. The function of the multiplexor board is defined in the Software Requirements Specification (SRS) for the modified device. The software verifies the state of each switch before enabling RF delivery. The performance of the multiplexor board within the modified truSculpt device was verified and validated during software V&V testing. All tests were passed. There were no exceptions.

Software verification and validation was performed, and it was demonstrated that the software for the modified truSculpt device performs as intended (V0174 – Software Verification and Validation Report).

Summary of Technological Characteristics:

The modified truSculpt RF device has the same intended use and indications for use and the same fundamental scientific technology as the previously cleared unmodified Cutera truSculpt RF device (K162512). It also has the same fundamental scientific technology as the Syneron SlimShape System (K163415) predicate device. The adjustable belt system and patient comfort switch that enable hands-free operation are very similar to the belts and comfort switches employed by the Syneron SlimShape System predicate device and the Cynosure SculpSure (K160470) reference device.

For each of the devices:

- the user interface is located at the front/top of the console;
- the treatment applicators are positioned on the patient's body prior to commencing treatment and held in place by adjustable belts;
- the devices moderately heat the superficial tissue of the patient to achieve their intended outcome; and
- the patient can terminate the treatment if the discomfort becomes excessive.

The modified truSculpt RF device employs the same fundamental scientific technology, similar key design aspects, and the same or similar treatment areas as its predicate and reference devices. Therefore, the minor differences do not raise any new safety or effectiveness questions.

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.