July 13, 2022

Cutera Inc.
Mr. Amogh Kothare, M.S.
VP Clinical and Regulatory Affairs
3240 Bayshore Blvd.
Brisbane, California 94005

Re: K221407
Trade/Device Name: truSculpt iD
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: May 31, 2022
Received: June 2, 2022

Dear Mr. Kothare:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221407

Device Name
truSculpt iD

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 2MHz setting for the 40cm2 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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K221407
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.

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|---|---|
| Applicant: | Cutera, Inc. |
| Address: | 3240 Bayshore Blvd<br>Brisbane, CA 94005 |
| Contact Person: | Mr. Amogh Kothare, MS<br>VP Clinical and Regulatory Affairs<br>3240 Bayshore Blvd<br>Brisbane, CA 94005<br>akothare@cutera.com<br>m. (415) 690-6796<br>o. (415) 657-5730<br>f. (415) 715-3730 |
| Preparation Date: | July 12, 2022 |
| Device Trade Name: | truSculpt iD |
| Common Name: | Massager, Vacuum, Radio Frequency Induced Heat |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories<br>GEI, PBX, 21 CFR 878.4400 |
| Primary Predicate Device: | truSculpt RF Device (K172004) |
| Secondary Predicate Device: | truSculpt RF Device; truSculpt; truSculpt 3D (K180709) |
| Intended Use: | The truSculpt iD 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.<br><br>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.<br><br>The truSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite. |

| | |
|---|---|
| Device Description: | The truSculpt iD device consists of a console, one or more RF handpieces that connect to the console with umbilical cables, 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. |
| Summary of Technological Characteristics: | The truSculpt iD device has similar technological characteristics as the primary and secondary predicate devices. The truSculpt RF Device, truSculpt, truSculpt 3D, and truSculpt iD are all comprised of a console and RF applicators. The consoles for all devices consist of a mechanical enclosure, an RF generator, control electronics, a touchscreen user interface, and a control microprocessor.<br><br>The shape and dimensions of the truSculpt iD RF handpieces are identical to those of the primary predicate device. The handpieces are now held in place by adhesive decals and a silicone belt, which are manufactured from biocompatible materials.<br><br>The truSculpt iD device heats tissue through delivery of RF energy at 1 MHz and 2 MHz, which is identical to the primary and secondary predicate devices. |
| Performance Data: | • IEC 60601-1/A1:2012 Medical Electrical Equipment – Part 1: General Requirements for Safety<br>  ○ IEC 60601-2-2:2009 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<br>  ○ IEC 60601-1-6:2010/A1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability<br>• IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests<br>• Software Verification and Validation Testing<br>• Biocompatibility testing of patient-contact materials according to ISO-10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process<br>• Skin temperature testing on 3 human subjects to demonstrate the skin temperatures do not exceed 45°C during the course of the treatment |
| Clinical Data: | None |

Technical Comparison to Predicate Devices:

| | **truSculpt iD Device (current submission)** | ***Primary Predicate Device*** **Cutera truSculpt RF Device (K172004)** | ***Secondary Predicate Device*** **Cutera truSculpt RF Device (K180709)** |
|---|---|---|---|
| Energy type | Radiofrequency | Radiofrequency | Radiofrequency |
| Massage | Yes | Yes | Yes |
| Temperature sensing | Yes | Yes | Yes |
| Temperature sensing active control | Yes | Yes | Yes |
| Treatment activation | Control screen button or fingerswitch | Control screen button or fingerswitch | Fingerswitch |
| Area treated | Handheld: 16 and 40 cm²<br>Hands-free: 40 to 240 cm² | Handheld: 16 and 40 cm²<br>Hands-free: 40 to 240 cm² | Handheld: 16 and 40 cm² |
| Electrode shape | Square or Rectangle | Square or Rectangle | Square or Rectangle |
| RF frequency | 1 MHz and 2 MHz | 1 MHz and 2 MHz | 1 MHz and 2 MHz |
| RF type | Bipolar/Monopolar | Bipolar/Monopolar | Bipolar/Monopolar |
| Max RF power | 300 W | 300 W | 300 W |
| Patient contact material | • Polyvinylidene fluoride (PVDF) for handheld handpieces<br>• Liquid resin adhesive for patient decals (for hands-free handpieces)<br>• Silicone for cummerbund (for hands-free handpieces)<br>• Hydrogel for neutral electrode pads<br>• Stainless steel for massage roller | • Polyethylene (3M Tegaderm) for handheld and hands-free handpieces<br>• Hydrogel for neutral electrode pads<br>• Stainless steel for massage roller | • Polyethylene (3M Tegaderm) for handheld handpieces<br>• Hydrogel for neutral electrode pads<br>• Stainless steel for massage roller |
| Attachment of hands-free handpieces to patient | Adhesive patient decals and cummerbund | Cloth belt | Not Applicable |

Conclusion: The truSculpt iD device has equivalent technological characteristics and principles of operation as the primary and secondary predicate devices.

Performance data demonstrates that any differences between the truSculpt iD and its predicate devices do not raise new safety or effectiveness questions. Skin temperature testing on three subjects further demonstrates that the truSculpt iD device can maintain therapeutic temperatures of 40°-45°C on the surface of the human skin and that maximum skin temperatures do not exceed 45°C.

The truSculpt iD device is substantially equivalent to the predicate devices.