



November 3, 2022

Cutera Inc.
Julia Brown
Sr Manager, Regulatory Affairs
3240 Bayshore Blvd.
Brisbane, California 94005

Re: K223110

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: September 30, 2022
Received: October 3, 2022

Dear Julia Brown:

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

Indications for Use

510(k) Number (if known)
K223110

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 40 cm² 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.

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K223110
510(k) Summary

This 510(k) Summary of safety and effectiveness for the truSculpt iD 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: Ms. Julia Brown
Sr. Manager, Regulatory Affairs
3240 Bayshore Blvd
Brisbane, CA 94005
jbrown@cutera.com
m. (415) 672-1858
o. (415) 657-5575
f. (415) 715-3575

Preparation Date: September 30, 2022

Device Trade Name: truSculpt iD

Common Name: Massager, Vacuum, Radio Frequency Induced Heat

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulation Number: 21 CFR 878.4400

Product Codes: GEI, PBX

Primary Predicate Device: truSculpt iD (K221407)

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.

Additionally, the 2 MHz setting for the 40 cm² 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.

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510(k) Summary

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:	<p>The modified truSculpt iD device has similar technological characteristics as the existing truSculpt iD device (K221407). Both devices comprise a console and RF applicators. The consoles for both devices consist of a mechanical enclosure, an RF generator, control electronics, a touchscreen user interface, and a control microprocessor.</p> <p>The modified truSculpt iD device includes a new 2 cm² RF applicator. The RF applicators of the modified and existing truSculpt iD devices are constructed of the same materials and have similar functional features and capabilities.</p> <p>The modified truSculpt iD device heats tissue through delivery of RF energy at 1 MHz and 2 MHz, which is identical to the existing truSculpt iD device.</p>
Performance Data:	<ul style="list-style-type: none">• Skin temperature testing on 3 human subjects to demonstrate that the 2 cm² RF applicator can maintain therapeutic temperatures of 40°-45°C on the skin surface and that skin temperatures do not exceed 45°C during the course of the treatment• Software verification and validation testing
Clinical Data:	Not applicable; non-clinical performance testing (as provided above) is sufficient to demonstrate substantial equivalence.

Table 5A—Technical Specification Comparison of Modified Device to Existing Device

	Modified truSculpt iD Device (current submission)	Existing truSculpt iD Device (K221407)
Energy type	Radiofrequency	Radiofrequency
Massage	Yes	Yes
Temperature sensing	Yes	Yes
Temperature sensing active control	Yes	Yes
Treatment activation	Control screen button or fingerswitch	Control screen button or fingerswitch
Area treated	Handheld: 2-40 cm ² Hands-free: 40-240 cm ²	Handheld: 16-40 cm ² Hands-free: 40-240 cm ²
Electrode shape	Square or Rectangle	Square or Rectangle
RF frequency	1 MHz and 2 MHz	1 MHz and 2 MHz
RF type	Bipolar/Monopolar	Bipolar/Monopolar
Max RF power	300 W	300 W
Patient contact material	<ul style="list-style-type: none"> • Polyvinylidene fluoride (PVDF) for handheld handpieces • Liquid resin adhesive for patient decals (for hands-free handpieces) • Silicone for cummerbund (for hands-free handpieces) • Hydrogel for neutral electrode pads • Stainless steel for massage roller 	<ul style="list-style-type: none"> • Polyvinylidene fluoride (PVDF) for handheld handpieces • Liquid resin adhesive for patient decals (for hands-free handpieces) • Silicone for cummerbund (for hands-free handpieces) • Hydrogel for neutral electrode pads • Stainless steel for massage roller
Attachment of hands-free handpieces to patient	Adhesive patient decals and cummerbund	Adhesive patient decals and cummerbund

K223110
510(k) Summary

Conclusion: The modified truSculpt iD device has equivalent technological characteristics and principles of operation as the existing truSculpt iD device (K221407). Cutera performed a detailed risk analysis of the modified device to assess the impact of the changes, and no new risks were identified.

Performance data demonstrates that any differences between the modified and existing truSculpt iD devices do not raise new safety or effectiveness questions. Skin temperature testing with the 2 cm² RF applicator on three human subjects further demonstrates that the modified truSculpt iD device can maintain therapeutic temperatures of 40°-45°C on the skin surface and that maximum skin temperatures do not exceed 45°C.

The addition of the 2 cm² RF applicator only impacts the relief of pain and muscle spasms and increase in local circulation indications. The reduction in circumference and lipolysis indications are achieved through the use of the 2 MHz setting for the 40 cm² handpiece, and the cellulite indication is achieved through the use of the truSculpt massage device.

The modified truSculpt iD device is substantially equivalent to the existing truSculpt iD device.