March 9, 2026

S&M Medical Co., Ltd.
% Edward Park
RA Consultant
Lighten Bridge LLC
4408 Tortuga Ln
McKinney, Texas 75070

Re: K252888
Trade/Device Name: NeoSculpt Plus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: February 3, 2026
Received: February 3, 2026

Dear Edward Park:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.03.09 10:08:18 -04'00'

Colin Kejing Chen, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252888

Device Name
NeoSculpt Plus

Indications for Use *(Describe)*
The NeoSculpt Plus 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.

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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510(k) Summary – Traditional 510(k)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information

Submitter Name:	S&M Medical Co., Ltd.
Address:	Suite 212, 249 Chuam-ro, Buk-gu, Gwangju 61003 Republic of Korea
Phone	+82-62-602-0820
Contact Person:	Edward Park, official correspondent of Biounit CO., LTD.
Preparation Date:	September 10, 2025

Device Information

Proprietary Name(s):	NeoSculpt Plus
Common Name:	General Purpose RF Therapeutic Device
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	PBX
Regulation Number:	21 CFR 878.4400
Classification Panel:	General & Plastic Surgery
Device Class:	II

Device Description

The NeoSculpt Plus is a medical device designed for use by medical professionals in hospital settings. It delivers Radiofrequency (RF) energy to a patient for therapeutic treatment. The system is composed of a main console, one or more RF handpieces that connect to the console via umbilical cables, and neutral electrodes that attach to the patient's skin.

The NeoSculpt Plus provides topical heating to elevate tissue temperature, which can be used to treat various medical conditions, including the relief of pain and muscle spasms and to increase local circulation. The system operates by generating a high-frequency current that flows from the handpiece, through the patient's body (which acts as a resistance), and back to the console via the neutral electrode. This intensive current flow generates a heating profile that produces a moderate temperature rise in the subcutaneous tissue.

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Predicate Device

truSculpt iD (Cutera, Inc., K223110)

- Regulation Name: Electrosurgical cutting and coagulation device and accessories
- Device Class: II
- Product Code: GEI
- Regulation Number: 21 CFR 878.4400
- Classification Panel: General & Plastic Surgery

Indications for Use

The NeoSculpt Plus 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.

Technological Characteristics

The NeoSculpt Plus retains the same basic design components and operating features as the predicate device, truSculpt iD. The functionality of the user interface is also the same as the predicate device. The design of the subject device's main console is also similar to that of the predicate device.

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Substantial Equivalence Discussion

NeoSculpt Plus has been compared to the following predicate device.

Device Name	**Proposed Device**	**Predicate Device**	**Remark**
	NeoSculpt Plus	**truSculpt iD**	
510k number		**K223110**	
Manufacturer	**S&M Medical Co., Ltd.**	**Cutera Inc.**	
Product Code	PBX	GEI, PBX	Identical
Regulation Number	878.4400	878.4400	Identical
Indications for Use	The NeoSculpt Plus 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.	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 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.	Substantially Equivalent The differences in the indications for use do not constitute a new intended use.
Prescription or OTC	Prescription Use Only	Prescription Use Only	Identical
Intended Patient Population	All ages	All ages	Identical

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Device Name	**Proposed Device**	**Predicate Device**	**Remark**
	NeoSculpt Plus	**truSculpt iD**	
510k number		**K223110**	
Manufacturer	**S&M Medical Co., Ltd.**	**Cutera Inc.**	
Operational Principle	The electrosurgical generator is the source of the electron flow and voltage. The circuit is composed of the generator, active electrode, patient and patient return electrode. The patient's tissue provides the impedance, producing heat as the electrons overcome the impedance. This heat elevates soft tissues' temperature and causes 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 noninvasive lipolysis (breakdown of fat) of the abdomen.	The electrosurgical generator is the source of the electron flow and voltage. The circuit is composed of the generator, active electrode, patient and patient return electrode. The patient's tissue provides the impedance, producing heat as the electrons overcome the impedance. This heat elevates soft tissues' temperature and causes 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 noninvasive lipolysis (breakdown of fat) of the abdomen.	Identical
ESU			
RF type	Monopolar	Monopolar	Identical
Temperature sensors	Yes	Yes	Identical
Impedance monitor	Yes	Yes	Identical

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Device Name	**Proposed Device**	**Predicate Device**	**Remark**
	NeoSculpt Plus	**truSculpt iD**	
510k number		**K223110**	
Manufacturer	**S&M Medical Co., Ltd.**	**Cutera Inc.**	
Continuity monitor	Yes	Yes	Identical
Performance specifications	Output frequency: 1 MHz and 2 MHz Waveform: Square or Rectangle Power output: 260 W max. Voltage output: 200V_{rms}	Output frequency: 1 MHz and 2 MHz Waveform: Square or Rectangle Power output: 300 W max. Voltage output: 250 V_{rms}	Substantially Equivalent
Physical specifications	**Dimension** 410mm (W) × 410mm (D) × 1130mm (H) **Weight**: 43.5 kg	**Dimension** 355mm (W) × 444.5mm (D) × 1054.1mm (H) **Weight:** 22.7 kg	Substantially Equivalent
Software User Interface	Display panel	Display panel	Identical
Display type	LCD with Capacitive Touch Screen	LCD with Capacitive Touch Screen	Identical
Target Temperature Range & Accuracy	40˚C ~ 45˚C (0.5˚C increment)	38˚C ~ 45˚C (0.5˚C increment)	Substantially Equivalent
Treatment Duration	Handsfree (40cm^2 handpiece): 15min. Handheld (40cm^2 handpiece): 3min. Handheld (16cm^2 handpiece): 3min.	Handsfree (40cm^2 handpiece): 15min. Handheld (40cm^2 handpiece): 15min. Handheld (16cm^2 handpiece): 5min.	Proposed Device ≤ Predicate

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Device Name	**Proposed Device**	**Predicate Device**	**Remark**
	NeoSculpt Plus	**truSculpt iD**	
510k number		**K223110**	
Manufacturer	**S&M Medical Co., Ltd.**	**Cutera Inc.**	
Active accessory - Handpiece			
Electrode type	Monopolar	Monopolar	Identical
Area treated	16cm^2, 40cm^2 handpiece	16cm^2 ~ 40cm^2 handpiece	Substantially Equivalent
Rated voltage	200V$_{rms}$	250 Vrms	Substantially Equivalent
Frequency	1 MHz and 2 MHz	1 MHz and 2 MHz	Identical
Impedance Matching	100 - 200 Ω range	100 - 200 Ω range	Identical
Maximum Power	130 Watts × 2 ea	150 Watts × 2 ea	The Subject device has lower max.power and lower max.power density than the predicate.
Temperature Monitoring	Yes	Yes	Identical
Neutral electrodes (K092761)			
Conductive or capacitive	Conductive	Conductive	Identical

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Device Name	**Proposed Device**	**Predicate Device**	**Remark**
	NeoSculpt Plus	**truSculpt iD**	
510k number		**K223110**	
Manufacturer	**S&M Medical Co., Ltd.**	**Cutera Inc.**	
Physical Type	Split Plate	Split Plate	Identical
Physical Dimension	136cm^2	136cm^2	Identical
Material	Aluminum foil + conductive gel	Aluminum foil + conductive gel	Identical
Contact Quality Monitoring	Yes	Yes	Identical

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Discussion

The subject and predicate devices are based on the following same technological elements:

- All devices use electrical energy to generate high-frequency (RF) energy as a means to elevate the temperature of target soft tissues.
- All instrument sets are comprised of ergonomic user interface (e.g. handpiece, neutral electrode, user stop switch, etc.) and connectors (e.g. cable) to the ESU.
- The handpieces of the subject device come in two configurations, namely handheld mode and a handsfree mode. These modes are consistent with those of the predicate device which also comes in the two configurations.
- The handpieces are for multiple use and provided non-sterile.

Some differences in their technological characteristics, including power output, voltage output, and physical specifications do not raise different questions of safety and effectiveness, as demonstrated by the following data:

- Performance Specifications
  The NeoSculpt Plus has a lower maximum power output (260 W) and a lower voltage output (200 V_{rms}) compared to the truSculpt iD (300 W and 250 V_{rms}). These differences in performance are addressed and justified by the accompanying bench test report and electrical safety test report. These reports confirm that despite the lower power and voltage, the NeoSculpt Plus still achieves the same therapeutic effects as the predicate device without compromising safety.
- Physical Specifications
  The overall dimensions and weight of the console units are different. The NeoSculpt Plus is larger and heavier than the truSculpt iD, and the physical design and dimensions of the handpieces also differ. The usability report demonstrated that the physical specifications of the subject device do not impact the device's fundamental function or raise new safety or effectiveness concerns.

Non-clinical test was performed in accordance with the following international standards,

A. Electromagnetic Compatibility and Electrical Safety Test

- AAMI ANSI ES60601-1:2005+AMD1:2012, Medical Electrical Equipment – Part 1; General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
- 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
- IEC 60601-1-6:2010+AMD1:2013, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability

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- IEC 60601-2-2:2017, Medical Electrical Equipment – Part 2 Particular Requirements for Basic Safety and Essential Performance of high frequency surgical equipment and high frequency surgical accessories

B. Bench Test

The NeoSculpt Plus demonstrated substantial equivalence to the predicate TruSculpt iD through comprehensive bench testing. Testing confirmed the accuracy of technical parameters (frequency, power, and timing) and validated the device's ability to maintain target skin temperatures (40.0 °C to 45.0 °C) on human subjects. Verification of safety monitoring and alarm systems further supports the conclusion that the device is as safe and effective as the predicate.

C. Software Verification and Validation

- ANSI AAMI IEC 62304:2006, Medical Device Software – Software Life Cycle Processes
- ANSI AAMI IEC 62366, Medical devices Part 1: Application of usability engineering to medical devices
- EN ISO 14971:2007 Medical devices - Applications of risk management to medical devices
- FDA Guidance for Content of Premarket Submissions for Device Software Functions

System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met, and all software hazards have been mitigated to acceptable risk levels.

Conclusion

The subject device is substantially equivalent in the areas of indications for use, general functions & features, principle of operation, technological characteristics, and applicable safety standards. The new device does not introduce fundamentally new scientific technology, and the successful results of bench testing and clinical accuracy validation should be sufficient evidence of substantial equivalence. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.