March 19, 2025

ShenB Co., Ltd
% Aubrey Thompson
Regulatory Consultant
Hoy and Associates Regulatory Consulting
1830 Bonnie Way
Sacramento, California 95825

Re: K242241
Trade/Device Name: Sunny
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, NFO, PBX
Dated: February 18, 2025
Received: February 18, 2025

Dear Aubrey Thompson:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.03.19 00:00:52 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242241

Device Name
Sunny

Indications for Use *(Describe)*
The Sunny RF Handpiece (6.78MHz) is indicated for Dermatologic procedures for electrocoagulation and hemostasis.

The Pulsar handpiece (1MHz and 2MHz RF) is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, 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
Sunny™
K242241

Applicant	ShenB Co., Ltd.
Address	SHENB Tower, 74, Achasan-ro, Seongdong-gu, Seoul, Korea, Republic of
Contact Person	Aubrey Thompson, Regulatory Consultant
Contact Information	aubreythompson@hoyregulatory.com
Preparation Date	March 17, 2025
Device Trade Name	Sunny™
K Number	K242241
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	878.4400
Product Code	GEI, PBX
Regulatory Class	II
Legally Marketed Predicate Device	Thermage CPT (K173759)
Reference Device	Nuera Tight

Device Description:
The Sunny device is a high frequency electrosurgical unit that conveys current to the human body through non-invasive electrodes. The device includes three different high frequencies: 6.78MHz (RF), 1MHz (RF), and 2 MHz (RF). It is composed of the main body, Sunny handpiece, Pulsar handpiece, treatment tips, neutral electrode pad, refrigerant gas, and foot switch. The device is operated through a graphic user interface on an LCD screen and is intended to be operated by medical professionals.

Indications for use:

The Sunny device has different indications for use according to its different modes.

The **Sunny RF Handpiece** (6.78 MHz) is indicated for dermatologic procedures for electrocoagulation and hemostasis.

The **Pulsar handpiece** (1MHz and 2MHz RF) is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

510(K) Summary
Sunny™
K242241

Indications for Use Comparison

Indications for Use Comparison			
Sunny ™ (Subject Device)	**Thermage CPT (K173759)**	**Nuera Tight RF (K210867)**	**Comparison**
The Sunny RF Handpiece (6.78MHz) is indicated for dermatologic procedures for electrocoagulation and hemostasis. **The Pulsar handpiece (1MHz and 2MHz RF)** is indicated to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.	The radiofrequency energy delivery components of the Thermage CPT System and Accessories are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis; • Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; • Non-invasive treatment of wrinkles and rhytids. The simultaneous application of radiofrequency energy and skin vibration by the Thermage CPT System and Accessories are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis; • Non-invasive treatment of periorbital wrinkles and rhytids; • Non-invasive treatment of wrinkles and rhytids;	Provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation; to provide, with a massage device, a temporary reduction in the appearance of cellulite.	The subject device and predicate device share the electrocoagulation and pain relief indications for RF devices. The Sunny RF handpiece has not been tested for wrinkle related indications and therefore does not include them in this submission. The subject device has the same indications for use as the reference device.

	• Temporary improvement in the appearance of cellulite; • Relief of minor muscle aches and pains; • Relief of muscle spasms; • Temporary improvement of local circulation (i.e., blood circulation).		

Technical Characteristics Comparison

SUNNY Handpiece Technical Specifications Comparison			
Specification	**Sunny™ (Subject Device)**	**ThermageCPT (Predicate Device)**	**Comparison**
Energy Delivery	**Sunny Handpiece:** Monopolar Radiofrequency	Monopolar Radiofrequency with vibration	Same.
Frequency	**Sunny Handpiece:** 6.78 MHz	6.78 MHz	Same.
Max power	**Sunny Handpiece:** 120 W	400 W	Different. Thermal Effects testing demonstrates effectiveness of the Sunny device at lower max power and desirable clinical effects from both devices as clinically relevant settings. See discussion below.
Energy Output	25 to 135 Joules	20 to 137 Joules	Similar. The small differences do not impact

Range			the safety or effectiveness of the subject device.
Electrode size	2.25 cm2	0.25 cm2, 3.0 cm2, and 16.0 cm2	The treatment area of the predicate device is slightly larger than the subject. Other tips are included with the Thermage that are not included with the Sunny.
Pulse width	1140ms	100-2000 pulses delivered during treatment (length of pulse is unknown)	Different, but overall energy output range is nearly the same.
Power Density	53.3 J/cm^2	45.6J/cm^2	Similar. The slight difference in electrode size creates the difference in power density, but the overall output energy range is very similar.
Energy Levels	16 power levels Level 0.5 = 20W @400Ω rated load Level 8.0 = 120W @400Ω rated load	19 power levels	similar
Duty Cycle	81.4%, intermittent Use	50%, intermittent Use	Different. Overall energy output range is nearly the same and the difference does not introduce any safety issues.
Operating modes	Soft mode- gradually increased power during a single pulse Hard mode – full power delivered (at selected level) during a single pulse	N/A	Different. Predicate device does not have a soft mode function. This does not impact safety or effectiveness, it is only intended to increase patient comfort.
Sterilization	Electrode tips are single use, not provided sterile	Electrode tips are reusable, not provided sterile	Neither device utilizes sterile tips, but the predicate device requires pre-use cleaning.
Biocompatibility	Materials contact intact patient skin with a contact duration of under 24	Materials contact intact patient skin with a contact duration of	Same.

	hours. Materials have been determined to be biocompatible through testing.	under 24 hours. Materials have been determined to be biocompatible.	

Pulsar Handpiece Technical Specifications Comparison				
	Sunny Device, Pulsar Handpiece	**Thermage CPT (Predicate Device)**	**Nuera Tight RF (Reference Device)**	**Comparison**
Energy Delivery	Monopolar and Bipolar Radiofrequency	Monopolar Radiofrequency with vibration	Monopolar and Bipolar Radiofrequency	The subject and predicate devices contain monopolar functionality. The Sunny Device also contains bipolar functionality. This does not impact the safety and efficacy of the device. The subject and reference devices both have monopolar and bipolar functionality.
Frequency	1MHz, 2MHz	6.78MHz	470 kHz; 1 MHz; 2 MHz; 4 MHz; 6 MHz	Different. Tissue temperature testing demonstrates that the devices can perform equivalently. The subject devices share the 1Mhz and 2MHz frequencies with the reference device.
Max power	40.5W at 1MHz	400W (treatment is	250W	Max power is higher with

	20.2W at 2MHz	recommended at lower power)		the predicate device. However, Thermage labeling recommends using a lower power to ensure patient comfort. Side by side testing was conducted at power levels that were similar for the two devices and demonstrates comparable performance.
Pulse Width	100 msec ~ 800 msec ± 10%	Unknown	Unknown	The exact pulse width of the predicate is unknown, but the output energy is very similar between the devices.
Sterilization	Not sterile	Not sterile	One handpiece is sterilize (ETO), other handpieces are not provided sterile	Same
Patient Contacting Materials	Intact skin contacting <24 hours Determined biocompatible through testing	Intact skin contacting <24 hours Determined biocompatible	Intact skin contacting <24 hours Determined biocompatible	Same
Performance goals	Temporary pain relief and increased circulation through topical heating. Maintenance of therapeutic temperature (40-43°C) for 10 mins of treatment.	Temporary pain relief and increased circulation through topical heating	Temporary pain relief and increased circulation through topical heating. Maintenance of therapeutic temperature (40-42°C +/- 2°C) for 15 mins of treatment.	Testing performance goals are the same for the subject and reference devices. Subject and Predicate devices share the same indications for use and performance testing demonstrates the predicate device can perform the same when

				subjected to the same test methods as the Sunny device.
Energy levels	10 levels Level 1: 1MHz: 15.2 W @ 200 Ω 2 MHz: 7.6W @200 Ω Level 10: 1 MHz: 40.5W @200 Ω 2 MHz: 20.2W @200 Ω	19 levels		The exact energy used at various levels for the predicate is not known.
Power density (total power per unit of area)	60 J/cm^2	45.6J/cm^2		Similar.
Tip configuration (pin spacing penetration, power each pin)	Blazar Cartidge: Flat, Square electrodes 2.25 cm^2 Quasar Cartridge: square electrodes with raised individual electrode pins, 25 or 36 pins, corresponding to 1.62 W/Pin or 1.13 W/Pin. Electrode size: 2.33cm2	Flat square electrodes, 0.25 cm2, 3.0 cm2, and 16.0 cm2	3.15cm^2, 7cm^2, 12.5cm^2, 28.25cm^2, 38.5cm^2, 78.5cm2	The 2.25 cm electrode is similar to the 3.0 cm electrode of the predicate device. The different sizes available with the Thermage are not available with the Sunny. The subject and reference device have slightly different designs. The reference device electrodes are circular and all flat. The smallest electrode of the reference device is similar in size to the Pulsar electrodes.
Operational modes pulse/continuous pulse cycles	Pulsed	Pulsed	Continuous	Same as predicate.

Treatment duration	10 minutes	unknown	15 minutes	Similar to reference device.
polarity	Monopolar, bipolar, combination of monopolar and bipolarity at varying ratios	Monopolar	Monopolar and bipolar electrodes	Both devices include monopolar functionality. The predicate device does not contain bipolar functionality. The bipolar function of the Sunny device is intended to provide flexibility in treatment options for the practitioner and does not impact the safety or effectiveness of the device.

Performance Testing

Verification and validation activities were successfully completed and establish that the Sunny™ performs as intended. Testing included the following:

- IEC 60601-1:2005 + A2:2020; Medical Electrical Equipment- Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014 + A1:2020; Medical Electrical Equipment- Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- IEC 60601-2-2:2017 + A1:2023; 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
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
- EN ISO 14971:2019; Medical Devices – Application Of Risk Management To Medical Devices
- IEC TR 60601-4-2 Edition 1.0 2016-05: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO 10993-1:2018 – Biological Evaluation of Medical Devices

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

Bench testing was performed to verify the accuracy of the output of RF energy. Histopathology testing was conducted to demonstrate the thermal effect of the device. A test summary is provided below.

A temperature maintenance test was performed for the Pulsar Handpiece and confirmed that the device can maintain skin temperature of 40°C-45°C for 10 minutes.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Biocompatibility – Patient contacting materials have been determined to be biocompatible.

Discussion

SUNNY RF Handpiece

The Sunny RF function at 6.78MHz shares the same general design, frequency, and intended use as the predicate, the Thermage CPT. The devices have the same frequency, but different maximum power outputs and slightly different electrode sizes. Thermal testing with the Sunny demonstrated that the device functions comparatively to the predicate. Based on the similarities between the two devices and the evidence of effectiveness provided by the thermal testing, the two devices can be considered substantially equivalent.

510(K) Summary
Sunny™
K242241

PULSAR RF Handpiece:
The Pulsar RF function shares the same intended use, mechanism of action, and general design as the predicate device. The two devices differ in output power and frequency, tissue temperature maintenance testing confirmed the device can maintain skin temperature of 40°C-45°C for 10 minutes of treatment on three different anatomical sites.

Conclusion:
Based on a comparison of indications for use, technological characteristics and performance data; it can be concluded that both the Sunny RF and Pulsar handpieces of the Sunny Device are substantially equivalent to the predicate device.