September 18, 2025

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

Re: K251649
Trade/Device Name: Sunny Plus (Sunny)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: August 25, 2025
Received: August 26, 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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.

Submission Number *(if known)*

K251649

Device Name

Sunny Plus (Sunny)

Indications for Use *(Describe)*

Low Frequency Electric Stimulator: This Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.

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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"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."

510(K) Summary
Sunny Plus
(K251649)

Sponsor	ShenB Co., Ltd.
Sponsor Address	SHENB Tower, 74, Achasan-ro, Seongdong-gu, Seoul, Republic of Korea
Sponsor Phone Number	82-2-4660010
Regulatory Contact Person	Aubrey Thompson, Regulatory Consultant
Contact Information	aubreythompson@hoyregulatory.com (530) 980-1602
Preparation Date	September 5, 2025
Device Name	Sunny Plus
Model Name	Sunny
Classification Name	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number	882.5890
Product Code	NFO
Regulatory Class	II
Legally Marketed Predicate Devices	TAMA BEMS (K173093)

Device Description:
The Sunny Plus device is a Low Frequency Electric Stimulator that conveys current to the human body through a non-invasive electrode with a frequency of 10Hz. It is composed of the main body, handpiece with electrode tip, 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:
Low Frequency Electric Stimulator: This Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.

Substantial Equivalence—Indications for use and Technical Comparison

Indications for Use Comparison		
Sunny Plus K251649	**TAMA BEMS K173093**	**Comparison**
Low Frequency Electric Stimulator: This Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes.	The TAMA BEMS Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes	Same

Technical Specifications Comparison			
Specification	**Subject device**	**TAMA BEMS**	**Comparison**

510(K) Summary
Sunny Plus
(K251649)

Mode of Operation	Application of transcutaneous electrical Nerve stimulation (TENS) through skin contact electrodes	Application of transcutaneous electrical Nerve stimulation (TENS) through skin contact electrodes	Same
Mode of Application	Metal and plastic electrodes in the	Metal and plastic electrodes in the system	Same
	system applicator emit electric energy to skin while the system applicator is moved across treatment area	applicator emit electric energy to skin while the system applicator is moved across or affixed to treatment area	
Body Application Areas	Face	Face	Same
Patient Leakage current Normal Condition (μA)	N/A (conformed to electrical safety standard)	N/A	Same
Patient Leakage current Single Fault Condition (μA)	N/A (conformed on electrical safety standard)	N/A	same
Number of output modes	1	4	Different. The subject device uses a single electrode, whereas the predicate device has different options for electrodes.
Number of output channels	1	1	Same
Regulated Current or Regulated Voltage?	Voltage	Both	Same
Software/Firmware/ Microprocess or Control?	Yes	yes	Same
Automatic Overload Trip	Yes	Yes	Same (over temperature control; see IEC 60601)
Automatic No Load Trip	Yes	yes	Same (Overcurrent circuit breaker; see IEC 60601)
Automatic shut off	Yes	yes	Same (Over current circuit breaker; see 60601)

Patient Override control	No	yes	Different. Treatment with subject device requires clinician to be present; patient is never left on their own for treatment, so a patient override control is not necessary.
Indicator display: On/off status	Yes	Yes	Same
Indicator Display: Low Battery?	N/A	Yes	N/A
Voltage/Current Level indicator?	Voltage	yes	Same
Timer Range	0-30 minutes	0-30 minutes	Same
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Same
Maximum Output Voltage (volts) (+/- 10%)	0.425VRMS@500Ω	±0.400 @500Ω	Different. Differences are minimal and do not impact safety or effectiveness.
	1.7VRMS@2000Ω	±1.600 @2 k Ω	
	8.5VRMS@10000Ω	±8.00 @10k Ω	
Maximum Output Current (mA@ Ω) (+/- 10%)	0.00085mA@500Ω	±0.800 @500 Ω	The output current for the subject device is lower than the predicate device, making it more comfortable for patient use.
	0.0002125mA@2000Ω	±0.800 @2 k Ω	
	0.0000425mA@10000Ω	±0.800 @10k Ω	
Pulse Width	100 to 400 µsec (.1-.4 msec)	52.6 – 2400 msec	The pulse width is shorter for the subject device than for the predicate device, making it more comfortable for patient use.

Frequency (Hz)	10Hz	0.045 – 2560 Hz	The frequency of the subject device is within the Frequency range of the predicate device. The predicate device has significant variability in its frequency, whereas the subject device has a fixed frequency.
Net Charge (microcoulombs (µC) per pulse) (If zero, state method of achieving zero net charge.)	0 @ 500Ω biphasic waveform Zero net charge is achieved by using symmetrical biphasic waveforms	0µC @500 Ω	Same
Maximum charge per Phase, (µC)	8.5µC positive phase, 8.5µC positive phase (0.4% duty cycle) , all loads	400 µC positive phase, 400 µC positive phase, (50% duty cycle), all loads	Different. The subject device generally delivers a lower stimulation than the predicate. The lower maximum charge per phase is safer for patients.
Maximum Current Density, (mA/cm²)	0.00354 mA/cm2 @ 500Ω	1.591 @500 Ω	Different
Maximum Power Density (W/cm²),	0.000376302 @500Ω	318E-6 @500Ω 0.012 @18.75 KΩ	similar.
Burst Mode (i.e., pulse trains):	N/A no burst mode	Pulses per burst - 5 - 20 Bursts per second - 10 - 40 Burst duration (seconds) 0.00195 – 0.0078 Duty Cycle: Line (b) x Line (c) 0.0195 – 0.1719	Different. The subject device does not contain a burst mode.

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 60601-2-10 + A2:2023; Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
- EN ISO 14971:2012; 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

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 power, current, and pulse width.

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

The Sunny Plus and the predicate device, TAMA BEMS, have the same principle of operation and the same essential performance characteristics: output voltage and frequency. The two devices function slightly differently, but not in a way that impacts device safety or effectiveness. The TAMA BEMS has multiple electrodes that can moved across a patient's face or be affixed to it, whereas the Sunny Plus has a single electrode that can be moved across the patient's face. The patient has no control during treatment, unlike the predicate device, making some patient-facing safety measures not applicable to the Sunny. The predicate device has a wider range of frequency than the Sunny Plus, with the Sunny Plus' 10Hz frequency falling at the lower end of the range. The pulse width, current, and current density of the two devices are different. The shorter pulse width of the Sunny Plus provides greater patient comfort, and the lower current delivers a lower sensation to the patient, while still stimulating tissue. These differences translate into higher levels of stimulation for the TAMA BEMS when used at these higher levels. Generally, the Sunny Plus has a subtler impact on nerve stimulation. The other differences in the devices do not impact the device safety or efficacy. Based on a comparison of indications for use, technological characteristics and performance data, it can be concluded that the Sunny Plus device is substantially equivalent to the predicate device.