September 3, 2025

A-1 Engineering
Anthony Picciano
CEO
30 Mauchly Ste A
Irvine, California 92618

Re: K251909
Trade/Device Name: NeurotriS (SX2500); NeurotriS (SX3800)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: February 6, 2024
Received: June 20, 2025

Dear Anthony Picciano:

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

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.

Submission Number *(if known)*

K251909

Device Name

NeurotriS (SX2500);
NeurotriS (SX3800)

Indications for Use *(Describe)*

The SX2500 / SX3800 Series devices uses microcurrent electrical energy 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510K Summary
K251909

Submitters Details:

Name: A-1 Engineering

Address: 30 Mauchly Ste A
Irvine, CA 92618

Phone Number: 951 537 7240

Email: tony@neurotris.com

Contact Person: Anthony Picciano

Date Prepared: 08/14/2025

Devices Trade Name: NeurotriS SX2500 Picowave
NeurotriS SX3800

Common Name: Transcutaneous electrical nerve stimulator for pain relief

Product Code: NFO

Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes

Regulation: 21 CFR 882.5890

Predicate Devices 1:

Name: TAMA Research Corp

510k Number: K173093

Product code: NFO

Predicate Devices 2:

Name: Biosonic Technologies LLC

510k Number: K130065

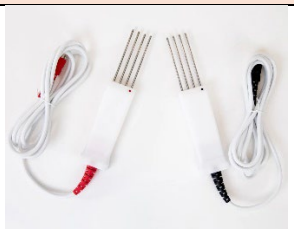
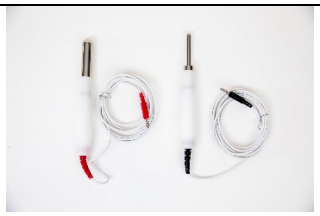
Product code: NFO

Device Description: The subject devices, SX2500 & SX3800, under the NFO Product Code, uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes.

Intended Use: The SX series uses applied accessories like probes , gloves or pads to deliver low electrical current to stimulation of facial tissues for aesthetic purposes.

The SX2500 & SX3800 is a powered microcurrent stimulator that uses electrical energy to stimulate facial tissues for aesthetic purposes. The SX2500 & SX3800 is substantially equivalent to the predicate devices compared in its product code class and has the same IFU. The SX2500 & SX3800 delivers signals independently to specific facial area points by way of channel ports via stainless steel probes and applicators substantially equivalent to the predicate device. The probes, gloves and pads referenced are the only patient contacting parts on the device that is substantially equivalent to the predicate device.

See table below of SX2500 and SX3800 Accessories / patient contacting parts substantially equivalent to the predicate devices

NeurotriS		TAMA 510K #173093	
Pico Probes		Probes	
ANMA Probe		Probes	
Infinity Probes		Probes	
		Con ductive Gel	

Spray		Tonic	
Pads		Lip & Square Electrode Pads	
Gloves		Conductive Gloves	

Non-clinical tests performed to demonstrate substantial equivalence.

Technological characteristics between the SX2500 and the SX3800 and those of the predicate devices were evaluated against the technical data found in the 510K on File with the FDA of the predicate devices.

Testing was performed at our Engineering test facility. The SX2500 and the SX3800 was BENCH tested against the Predicate devices as we have available the predicate devices at our facility to test. Technical Data found in the 510K of the predicate devices, and data obtained from the Bench testing was compared against the SX2500 and the SX3800 is substantially equivalent.

Summary of Technological characteristics compared showing substantial equivalence.

Technical Summary:

Indications for Use:	Substantial Equivalent
Number of Output Channels:	Substantial Equivalent
Regulated Current or Voltage:	Substantial Equivalent
Indicator Display Status:	Substantial Equivalent
Compliance with Voluntary Standards:	Substantial Equivalent
Compliance with 21 CFR 989:	Substantial Equivalent

Waveform:	Substantial Equivalent
Shape:	Substantial Equivalent
Symmetrical phases:	Substantial Equivalent
Phases Duration:	Substantial Equivalent
Net Charge:	Substantial Equivalent
Maximum Phase Charge:	Substantial Equivalent
Maximum Current Density:	Substantial Equivalent
Maximum Average Current:	Substantial Equivalent

Applicators:

Probes:	Substantial Equivalent
Conductive Gloves:	Substantial Equivalent
Pads:	Substantial Equivalent

Detailed Technological characteristics Tabular Comparison showing substantial equivalence

	NeurotriS SX3800 SX2500	TAMA BEMS Device – Subject Device K173093	Beautiful Image Model 900 Facial Toning Device – K130065
Indications for Use	The NeurotriS SX3800 SX2500 Devices uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes	The TAMA BEMS Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes	The Beautiful Image Model 900 Facial Toning Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic
Number of Output Ports	One to Four	One to Four	One to Two
Number of Output Channels Synchronous or Alternating?	One to Four N/A	One N/A	One N/A
Manufacturer	A1 Engineering	TAMA Research Corporation	Biosonic Technologies, LLC
Regulated Current or Regulated Voltage?	BOTH	Both	Both
Software/Firmware/Microprocessor	YES	Yes	Yes
Automatic Overload Trip?	Yes	Yes	Yes
Automatic No-Load Trip?	Yes	Yes	Yes
Automatic Shut Off?	Yes	Yes	Yes
User Override Control?	Yes	Yes	Yes
Indicator Display Status On/Off Display Status? Low Battery?	YES NA Yes	Yes Yes Yes	Yes Yes Yes

Timer Range (minutes)	20 minutes	0-30 minutes	None
Compliance with Voluntary Standards?	IEC60601-1	IEC60601-1	IEC 60601-1
Compliance with 21 CFR 989?	YES	Yes	Yes
Weight (lbs., oz.)	12 lbs	9.5 ounces	10 lbs
Dimensions (in.) [WxHxD]	10x11x6	3x5x0.7	5.5x15.3x11.3
Housing Materials and Construction	Anodized aluminum 6061	Anodized aluminum 6061	Thermoplastic
Waveform (e.g., pulsed monophasic,	Biphasic	Biphasic	Biphasic

Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-5%)	±0.500 @500Ω ±1.700 @2 k Ω ±7.50 @10k Ω	±0.400 @500Ω ±1.600 @2 k Ω ±8.00 @10k Ω	0.347 @500Ω 1.242 @2 k Ω 5.780 @10k Ω
Maximum Output Current (mA) (+/-5%)	±1.0 @500 Ω ±0.850 @2 k Ω ±0.790 @10k Ω	±0.800 @500 Ω ±0.800 @2 k Ω ±0.800 @10k Ω	0.647 @500 Ω 0.625 @2 k Ω 0.584 @10k Ω
Duration of primary (depolarizing) phase (msec)	220 – 1280	26.3 – 1200	0.648 – 322
Frequency (Hz) [or Rate (pps)]	.5 - 1250	0.045 – 2560	0.621 – 308.6
For multiphasic waveforms only: Symmetrical phases? Phases Duration (msec), (state range, if applicable), (both phases, if asymmetrical)	YES 220 - 1250	Yes 26.3 – 1200	Yes 0.324-161
Net Charge (micro coulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)	0μC @500 Ω	0μC @500 Ω	0μC @500 Ω
Maximum Phase Charge, (μC)	510 μC positive phase, (50% duty cycle), all loads	400 μC positive phase, 400 μC positive phase, (50%	190 @500 Ω
Maximum Current Density (mA/cm^2, r.m.s.)	1.421 @500 Ω **(1)**	1.591 @500 Ω **(1)**	1.486 @500 Ω
Maximum Average Current (average absolute value), mA	0.850 @500 Ω	0.800 @500 Ω	0.493 @500 Ω
Maximum Average Power Density, (W/cm^2), (using smallest electrode conductive surface area)	357E-6 @500Ω	318E-6 @500Ω **(2)** 0.012 @18.75 KΩ **(3)**	366E-6 @500 Ω
ON Time (seconds)	Constant	Constant	10-30
OFF Time (seconds)	None	None	1-6
Additional Features (specify, if applicable)	None	None	None

Basis for a determination of substantial equivalence.

The facial System has two models; SX2500 and SX3800. Both models utilize the same internal electrical components. The models differ in the control/display features and exterior casing/dimensions. Although the SX3800 model has more channels (1 to 4) than the predicate devices, identical isolated signals come from all channels. The SX2500 and SX3800 uses from 1 to 4 channels substantially equivalent to the predicate device that uses from 1 up to 4 ports. Detailed Technological characteristics Tabular Comparison above is showing substantial equivalence in all Parameters compared.

Nonclinical tests demonstrate substantial equivalence.

Both new Devices and the Predicate devices were bench tested at our facility and by third party testing facilities to the following safety standards for safe and effective use.

IEC 60601-1-2:2014 [Including AMD 1:2021]	Meets
Basic safety and essential performance: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), IEC 60601-1-11:2015+A1	Meets
Edition 4.1 EMC (IEC 60601-1-2:2020)	Meets
Biocompatibility testing was performed to: ISO 10993-1:2018	Meets

Test show that the SX series devices are safe, as effective, and performs as well as or better than the legally marketed device.

Testing has indicated that the output from all 4 channels simultaneously is substantially equivalent as compared to the output from the 1 channel of the predicate devices tested. Detailed Technological characteristics Tabular Comparison above shows substantial equivalence in ALL technical parameters compared. (technical characteristics and parameters were obtained from the predicate 510K's filed with the FDA)
The principles of operation and performance characteristics are substantial equivalence as the predicate device and pose no harm or risk to the user or patient.

Final Summary conclusion:

Therefore, the SX2500 and SX3800 Systems are substantially equivalent to the predicate device with technical characteristics, with Accessories / patient contacting parts, IFU, and performance characteristics. Test show that the SX series devices are safe, as effective, and performs as well as or better than the legally marketed device.