



FDA U.S. FOOD & DRUG
ADMINISTRATION

November 7, 2025

Sigma Biomedical
Jorge Millan, PhD
Regulatory Affairs Director
490 Sawgrass Corporate Parkway
Suite 130
Sunrise, Florida 33325

Re: K243131

Trade/Device Name: Triathlon Pro
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: October 8, 2025
Received: October 8, 2025

Dear Dr. Millan:

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,


Heather L. Dean -S

for Pamela Scott

Assistant Director

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

Indications for Use

Submission Number (if known)

K243131

Device Name

Triathlon Pro

Indications for Use (Describe)

TENS: The device is designed to be used for temporary relief of pain associated with the sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.

EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.

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

Submitter Information

Submitter	Globus Sport and Health Technologies LLC 7280 NW 7th St # 109 Miami FL 33126, USA
Contact:	Jorge Millan, PhD
Telephone number	(786) 416-5587
E-mail	jmillan@sigmabiomedical.com
Date prepared:	Oct 6, 2025

Subject Device Name

Trade/Proprietary Name:	Triathlon Pro TENS and EMS stimulator
Regulation Number:	21 CFR 882.5890, 21 CFR 890.5850
Regulation Name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief Powered muscle stimulator
Product Code:	NUH, NGX
Class	II

Primary Predicate Device

Predicate Device:	TENS & EMS Device (Model: FM-B2403A)
Sponsor	SHENZHEN JIAN FENG ELECTRONIC TECHNOLOGY CO., LTD.
510(K)	K213741
Regulation Number:	21 CFR 882.5890, 21 CFR 890.5850
Regulation Name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief Powered muscle stimulator
Product Code:	NUH, NGX
Class	II

Reference Device

Predicate Device:	Transcutaneous Electrical Nerve Stimulator (K6106)
Sponsor	Shenzhen Yicai Health Technology Co., Ltd.
510(K)	K241119
Regulation Number:	21 CFR 882.5890, 21 CFR 890.5850
Regulation Name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief Powered muscle stimulator
Product Code:	NUH, NGX
Class	II

Device Description:

The Globus Triathlon Pro TENS and EMS stimulator is an over-the-counter transcutaneous electrical nerve stimulator and electronic muscle stimulator (TENS/EMS) device providing peripheral nervous system stimulation and muscular electrostimulation in order to reduce atrophy, spasticity, and to increase muscular power. It can be used for arm, shoulder, neck, back, waist, abdomen, and legs.

The stimulation channels transfer the desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing muscle contractions. The accessory electrodes are FDA-cleared. They are used as an accessory to the TENS or EMS device unit, which transmits electrical current to the patient skin. The electrical current is first transmitted via the lead wire or snap button then transmitted to the conductive gel which is adhered to patient skin.

The Triathlon Pro provides electro stimulation through the surface electrodes. Electrode position during electro stimulation depends on the body part involved and on the type of program that is being carried out. For all programs that cause significant muscle contraction, it is important to place the electrode on the muscle motor point, which is the most sensitive to stimulation. The electro stimulator keeps track of the last 10 executed programs so that they are available for very simple and fast execution. Recording takes place automatically at the end of the execution of a program.

Electrostimulations are designed to be used in domestic environments, clinics, physiotherapy centers, rehabilitation in general, pain treatments in general, for aesthetic and sport purposes. The user of this device must be adult.

Indications for Use:

TENS: The device is designed to be used for temporary relief of pain associated with the sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.

EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.

Non-Clinical Data:

Non-clinical product evaluation was conducted to demonstrate safety and effectiveness and to verify the device meets all design specifications. The conducted tests support the conclusion of substantially equivalence to the predicate device. *The testing results demonstrate that the Triathlon Pro device complies with the following standards:*

IEC 60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

IEC60601-1-11, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC60601-2-10, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.

FDA software validation guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002

The body-contacting components of this device are 510(k)-cleared electrode patches, such as K092546, K160081 or equivalent FDA cleared EMS/TENS electrodes. The electrode patches comply to the following standards:

- 1) *ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests for In Vitro Cytotoxicity;*
- 2) *ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.*

Predicate Devices

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]:

The proposed system models are substantially equivalent to TENS and EMS electro stimulation devices cleared for marketing in the US. The Triathlon Pro is equivalent to the *TENS & EMS Device (Model: FM-B2403A)* by SHENZHEN JIAN FENG ELECTRONIC TECHNOLOGY CO., LTD. Cleared for marketing under K213741, and the reference predicate Transcutaneous Electrical Nerve Stimulator (K6106), FDA-cleared under K241119. The subject and predicate devices incorporate similar technological principles of operation, functionality and specifications.

Technical Characteristics Comparison:

The basic and main technical features of the subject device are similar as the predicate device.

Feature Comparison:

Subject device has similar features and functionality as the predicate device:

Product Comparison

Device Characteristic	Subject Device	Predicate Device	Comparison
Product Name	Triathlon Pro (K243131)	<i>FM-B2403A (K213741)</i>	N/A
Manufacturer	Globus Sport and Health Technologies LLC	<i>Shenzhen Jian Feng Electronic Technology Co. LTD</i>	N/A
510(k) Number	TBD	K213741	N/A
Product Code	NUH, NGX	NUH, NGX	Same
Regulation Number	<i>21 CFR 882.5890</i> <i>21 CFR 890.5850</i>	<i>21 CFR 882.5890</i> <i>21 CFR 890.5850</i>	Same
Classification	Class II	Class II	Same
Indications for Use	TENS: The device is designed to be used for temporary relief of pain associated with the sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.	Similar

	EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.	EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.	
Apply parts of the body	Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom	Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom	Same
Power Source	Ni-MH battery	Lithium battery	Difference
Method of Line Current Isolation	BF	BF	Same
- Patient Leakage Current	/	/	
- Normal condition	<10µA	<10µA	Similar
- Single fault condition	<50µA	<50µA	Similar
Number of Output Channels	4	4	Same
Synchronous or alternating	Synchronous	Synchronous	Same
Software Control?	Yes	Yes	Same
Compliance with Standards?	EN 60601-1 IEC60601-1-2 IEC 60601-2-10 IEC60601-1-11	ANSI/AAMI/ES 60601-1 IEC60601-1-2 IEC 60601-2-10 IEC60601-1-11	Same
Weight (g)	404g	86g	Different
Dimensions (mm) [D x W x H]	160x99x35.4	110*61*24	Different
Housing materials	ABS	ABS	Same
Waveform	Biphasic	Biphasic	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (volts)	64V @500Ω 176V @2kΩ 190V @10kΩ	Not Available	
Maximum Output Current (mA)	128mA @500Ω 88mA @2kΩ 19mA @10kΩ	196@500Ω 75@2KΩ 16.5@10KΩ	Similar
Maximum Average Current (mA)	8.64mA @500Ω 5.94mA @2kΩ 1.28mA @10kΩ	Not Available	
Pulse Duration (µs)	50-450	50-180	Difference
Frequency (Hz)	0.3-150	<199	Similar

<i>Net Charge (micro coulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)</i>	0.001@500 Ω	0.001@500 Ω	Same
<i>Maximum Phase Charge, (μC)</i>	57.6 μC @500 Ω	35 @500 Ω	
<i>Maximum Current Density (mA/cm^2)</i>	0.35 mA/cm^2 @500Ω with 5x5 cm electrodes	0.5645 mA/cm^2 @500 Ω	
<i>Maximum Average Power Density (mW/cm^2)</i>	1.49 mW/cm^2 @500Ω	Not Available	
<i>Burst durations (ms)</i>	100 ms	50 ms	

Comparison to the Reference Predicate

Device Characteristic	Subject Device	Reference Predicate	Comparison
Product Name	Triathlon Pro (K243131)	<i>Transcutaneous Electrical Nerve Stimulator (K241119)</i>	N/A
Weight (g)	404g	110g	Difference
Dimensions (mm) [D x W x H]	160x99x35.4	118 x 65 x 20	Similar
Pulse Duration (μs)	50-450	120-400	Similar

Evaluation of similarities and differences:

The Triathlon Pro has similar intended use, functionality, similar technologies as well as safety and performance characteristics than the *TENS & EMS Device (Model: FM-B2403A)*. The difference between the subject and main predicate device includes the battery type, physical dimensions, and pulse duration. The Triathlon Pro uses a NiMH battery which is considered safer and more stable, with fewer risks of leakage and thermal runaway than Lithium batteries, used by the main predicate. In terms of the size and weight, the difference is not considered a safety or effectiveness concern as it is related to the electronic design and board size. The pulse duration of the subject device is similar to the pulse duration of the reference device (K241119). We thus conclude that there are no differences among the subject and predicate devices that can impact or raise new issues of safety or effectiveness.

Conclusion:

The subject device has similar technological characteristics and has similar intended use and functionality as the predicate device. There are no differences between the devices that affect the usage, safety and effectiveness, thus no new question is raised regarding the safety and effectiveness. The non-clinical performance test data and software verification and validation demonstrate that the Triathlon Pro is as safe and effective as the predicate device. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, the Triathlon Pro is substantially equivalent to the predicate that is currently marketed for the same intended use.