March 12, 2026

Termosalud S.L.
℅ Connie Hoy
Regulatory Consultant
Hoy & Associates Regulatory Consulting, LLC
1830 Bonnie Way
Sacramento, California 95825

Re: K253636
Trade/Device Name: Zionic Pro Max (EMS)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: August 31, 2025
Received: November 19, 2025

Dear Connie Hoy:

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 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 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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253636

Please provide the device trade name(s).

Zionic Pro Max (EMS)

Please provide your Indications for Use below.

The Zionic Pro Max EMS function of the device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Zionic Pro Max programs is not suitable for rehabilitation or physiotherapy.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary
ZIONIC PRO MAX – EMS
K253636

Applicant	TermoSalud S.L.
Address	Ataulfo Friera Tarfe, 8 -33211 Gijón , Spain
Contact Person	Connie Hoy Consultant
Contact Information	conniehoy@hoyregulatory.com
Preparation Date	March 9, 2026
Device Trade Name	ZIONIC Pro Max EMS
Common Name	Electromagnetic Muscle Stimulator
Regulation Number	21 CFR 890.5850
Product Code	NGX
Regulatory Class	II
Legally Marketed Predicate Device	Compex Sport Elite 3.0 K201653

Device Description:
The ZIONIC Pro Max is an innovative electrical impulse generator that generates electrical muscle stimulation (EMS) energy to subcutaneous tissue by way of contact with intact skin. The device includes and console and user interface that power a selection of handpieces that deliver EMS to intact skin. The device is intended for use by medical professionals.

Indications for use:

The Zionic Pro Max EMS function of the device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Zionic Pro Max programs is not suitable for rehabilitation or physiotherapy.

Device Name, Model	Zionic Pro Max (Subject)	Compex Sport Elite 3.0 (primary predicate)	Comparison
510K #	K253636	K201653	N/A
Indication	Intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Zionic Pro Max programs is not suitable for rehabilitation or physiotherapy.	Intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Compex Sport programs are not suitable for rehabilitation or physiotherapy.	Same
Prescription Use/Over-the-Counter Use	Prescription Use	Over-the-Counter Use	The subject device is restricted to prescription use; however, it has the same intended use and comparable technological characteristics as the predicate. This difference does not impact safety or effectiveness and does not affect the determination of substantial equivalence.
Power Source *Line Voltage *Frequency *Isolation Method	120V, 60 Hz, 200VA *Galvanic isolation	* Li-ion rechargeaable 3.7V battery, *10 W	Different, Zionic Pro Max is AC Line powered whereas other predicates are battery powered. The power source does not impact safety or effectiveness in that it's output waveform etc. are substantially equivalent to the predicate device.

Device Name, Model	Zionic Pro Max (Subject)	Compex Sport Elite 3.0 (primary predicate)	Comparison
Number of Output Modes	One (NMES)	Two (NMES/TENS)	Different, Zionic provides only a single waveform type in both preset & free "modes". This waveform is used for NMES and the subject does not provide for a TENS type waveform. This difference does not impact safety or effectiveness.
Number of Output Channels *Synchronous or Alternating *Method of Channel Isolation	4 channels *synchronous but never 2 channels at same time *isolated by independent high Z H-bridges	4 channels *synchronous but never 2 channels at same time *isolated by independent high Z H-bridges	Same
Regulated Current or Voltage?	Regulated Current	Regulated Current	Same
Software/ Firmware/ µProc Control?	Yes	Yes	Same
Automatic Overload Trip?	Yes,	Yes	Same
Automatic No-Load Trip?	Yes	Yes	Same
Automatic Shut Off?	Yes	Yes	Same

Device Name, Model	**Zionic Pro Max (Subject)**	**Compex Sport Elite 3.0 (primary predicate)**	**Comparison**
Patient Override Control?	Yes, patient remote stop/ safety stop switch	Yes, On/Off switch pauses output	Same
Indicator Display *On/Off Status?	Yes, LCD display	Yes	Same
Indicator Display *Low Battery?	N/A	Yes	N/A
Indicator Display *Voltage/ Current Level?	Yes	Yes	Same
Weight	32 kg	.21 kg	Different, Zionic Pro Max is a floor standing unit whereas predicate is handheld. This difference does not impact safety and effectiveness.
Dimensions (inches) [W x H x D]	W: 68.4cm H: 142cm L: 64.6cm	W: 80mm H: 24.6mm L: 140mm	Different, Zionic Pro Max is a floor standing unit whereas predicates are handheld. This difference does not impact safety and effectiveness.
Housing Materials & Construction	Main case: polyurethane + metalic back panel. Handpieces: Polyamide 12.	Plastic ABS with PMMA windows, silicone	Different. This difference does not impact safety and effectiveness.
Waveform / Shape	*Symetrical bi-phasic square wave*	*Symetrical bi-phasic square wave*	Same
Maximum Output Voltage (± 10%)	*48 V @ 500 Ω* *162 V @ 2 kΩ* *178 V @ 10 kΩ*	*60 V @ 500 Ω* *165 V @ 2 kΩ* *165 V @ 10 kΩ*	Different; Considering the electrode impedance, this voltage acts to provide a max current density substantially equivalent to

Device Name, Model	Zionic Pro Max (Subject)	Compex Sport Elite 3.0 (primary predicate)	Comparison
			other class II PMS devices cleared under 21 CFR 890.5850 operate very close to this range (e.g., K940301 at 100mA). This difference does not impact safety or effectiveness.
Maximum Output Current (± 10%)	96 mA @ 500 Ω 81 mA @ 2 kΩ 17 mA @ 10 kΩ	120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ	Different; other class II PMS devices cleared under 21 CFR 890.5850 operate substantially equivalent to this range (e.g., K940301 at 100mA). This difference does not impact safety or effectiveness.
Pulse Width	610uS	200-400uS	Different; other class II PMS devices cleared under 21 CFR 890.5850 operate substantially equivalent to this range (e.g., K940301 at 15-800uS). This difference does not impact safety or effectiveness.
Pulse Frequency	3-40 Hz	1-120 Hz	Different . The pulse frequency is within the range of the cited predicate device. This difference does not impact safety and effectiveness.
Interferential Modes only *****Beat Frequency	N/A	N/A	N/A

Device Name, Model	**Zionic Pro Max (Subject)**	**Compex Sport Elite 3.0 (primary predicate)**	**Comparison**
Net Charge (µC/pulse) if zero state method	0µC @500Ω excitation pulse fully compensated	0µC @500Ω excitation pulse fully compensated	Same
Maximum Phase Charge (µC)	58 uC	48 uC	Different; 2 other class II PMS devices cleared under 21 CFR 890.5850 operate above and below this range (e.g., K940301, K011880). This difference does not impact safety or effectiveness.
Maximum Current Density	1.19mA/cm^2 @500Ω	1.49mA/cm^2 @500Ω	Different; Subject max current = 96mA vs. 120mA for cited predicate resulting in max current density ~25% below cited predicate although other class II PMS devices cleared under 21 CFR 890.5850 operate in this range (e.g., K940301). This difference does not impact safety or effectiveness.
Maximum Power Density	8.98mW/cm^2 @500Ωmw	27.6mW/cm^2 @500Ω	Different; Zionic max frequency is 40Hz Vs. 120Hz for cited predicate resulting in a lower max power density. At 40Hz, predicate = 9.2mW/cm^2. This difference does not impact safety or effectiveness.

Performance Testing
Verification and validation activities were successfully completed and establish that the ZIONIC Pro Max control unit performs as intended. Testing included the following:

- IEC 60601-1 Edition 3.2 2020-08; 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 60601-2-10:2012+AMD2:2023 specifies particular safety and performance requirements for nerve and muscle stimulators, including TENS and EMS devices used in physical medicine
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes;
- EN ISO 14971:2019+A11:2021; Medical Devices – Application Of Risk Management To Medical Devices

The biocompatibility evaluation for the Zionic Pro Max EMS device was conducted in accordance with the FDA guidance on "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'", and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

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.

Clinical Testing – no clinical testing was conducted as part of this submission

Comparison to the predicate device and conclusion
The subject device shares similar indications for use, general design, and technical parameters as the cited predicate device. The technological differences of the subject device do not impact the safety or effectiveness. It can be concluded, therefore, that the subject device is substantially equivalent to the predicate device.