November 21, 2025

Everyway Medical Instruments Co.,LTD
Jimmy Cheng
Vice President R&D Department of Everyway Medical Instruments Co., Ltd.
8Fl. No.5, Lane 155, Sec.3 Beishen Rd., Shenkeng Dist.
New Taipei City, 22203
Taiwan

Re: K251856

Trade/Device Name:	Li-Battery Powered OTC TENS/EMS Combination Stimulator, Model Z4
Regulation Number:	21 CFR 882.5890 and 21 CFR 890.5850
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief; and Powered muscle stimulator
Regulatory Class:	Class II
Product Code:	NUH, NGX
Dated:	May 2, 2025
Received:	June 17, 2025

Dear Jimmy Cheng:

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,

XIAORUI TANG -S

For: CDR Jitendra Virani, MS, MBA
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

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)*
K251856

Device Name
Li-Battery Powered OTC TENS/EMS Combination Stimulator, Model Z4

Indications for Use *(Describe)*
1. The Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator is intended for over-the- counter (OTC) use. It integrates both TENS and EMS functions in a single unit. However, the device can only operate in one mode (either TENS or EMS) at a time; simultaneous operation of both modes is not possible.
2. TENS is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P19 programs)
3. EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P20 to P30 programs)

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.

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I. SUBMITTER

Applicant: Everyway Medical Instruments Co., LTD.

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Date Prepared: Nov 20th, 2025

II. DEVICE

Name of Device: Li-Battery Powered OTC TENS/EMS Combination Stimulator, Model Z4

Common or Usual Name: Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator

Regulation Names: Transcutaneous electrical nerve stimulator for pain relief; and Powered muscle stimulator

Regulation Numbers: 21 CFR 882.5890 and 21 CFR 890.5850

Product Codes: NUH and NGX

Regulatory Class: II

III. PREDICATE DEVICE

510(k) Number: K201335

Name of Device: Li-Battery powered OTC TENS/EMS Combination Stimulator, Models EV-906/EV-906A

Regulation Names: Transcutaneous electrical nerve stimulator for pain relief; and Powered muscle stimulator

Regulation Numbers: 21 CFR 882.5890 and 21 CFR 890.5850

Product Codes: NUH and NGX

Regulatory Class: II

IV. DEVICE DESCRIPTION

The Li-Battery powered OTC TENS/EMS Combination Stimulator, model Z4, is a four-channel electrical stimulation device intended for pain relief and muscle training. It delivers electrical current through electrodes placed on the user's skin. Each operating mode delivers a fixed, pre-

configured waveform (e.g., asymmetrical bi-phasic square pulse) and output characteristics; users may only adjust intensity and treatment duration within predefined limits.

The device primarily consists of two components: the stimulation generator and adhesive electrodes. The generator produces the stimulation current, which is delivered to the body via lead wires connected to the electrodes. Depending on the selected mode—TENS or EMS—the device helps achieve either temporary pain relief or improved muscle performance.

The Z4 includes the following preset programs:

- TENS Mode (Programs P1–P19): Intended for temporary relief of pain in the lower back, arms, and legs due to exercise or household/work strain. Users are advised to begin with the lowest intensity and gradually increase to a comfortable “tingling” sensation. Each program differs in waveform parameters and may produce varied sensations.
- EMS Mode (Programs P20–P30): Designed to stimulate healthy muscles to enhance or support muscle performance. These programs cause the muscles to contract and relax. Users should start at low intensity for warm-up and increase gradually as needed.

The Z4 device package includes the following accessories:

- Adhesive Electrode Pads × 24
- Lead Wires × 4
- USB Cable × 1
- Instruction Manual × 1
- Carrying Case × 1

V. INDICATIONS FOR USE

1. The Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator is intended for over-the-counter (OTC) use. It integrates both TENS and EMS functions in a single unit. However, the device can only operate in one mode (either TENS or EMS) at a time; simultaneous operation of both modes is not possible.
2. TENS is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P19 programs)
3. EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P20 to P30 programs)

VI. COMPARISON WITH PREDICATE DEVICE

The subject device, Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator, is substantially equivalent to the predicate device EV-906/EV-906A (K201335) in terms of intended use, basic design, technological characteristics, and performance. Both devices are classified as Class II under product codes NUH (TENS) and NGX (EMS), and conform to the applicable regulations 21 CFR 882.5890 and 21 CFR 890.5850.

VI.1 Intended Use Comparison

Both the subject and predicate devices combine TENS and EMS functions in a single unit. They are intended for over-the-counter (OTC) use and can only operate in one mode at a time (TENS or EMS), not simultaneously.

- TENS function: Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.
- EMS function: Stimulation of healthy muscles to improve or facilitate muscle performance.

VI.2 Substantial Equivalence Table

A. Basic Unit Characteristics

Feature / Characteristic	New Device	Predicate Device	Same or Equivalent?	Explanation of Differences
510(k) Number	K251856	K201335	—	—
Device Name, Model	Li-Battery Powered OTC TENS/EMS Combination Stimulator, Model Z4	Li-Battery Powered OTC TENS/EMS Combination Stimulator, models EV-906/EV-906A	Same	--
Manufacturer	Everyway Medical Instruments Co., Ltd.	Everyway Medical Instruments Co., Ltd.	Same	--

Indications for Use	1. The Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator is intended for over-the-counter (OTC) use. It integrates both TENS and EMS functions in a single unit. However, the device can only operate in one mode (either TENS or EMS) at a time; simultaneous operation of both modes is not possible. 2. TENS is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P19 programs) 3. EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P20 to P30 programs)	•TENS: intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/ or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes B/N/M/SD1/SD2 as adjustable mode and P1 to P12 preset programs only for EV-906A). • EMS: intended to stimulate healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes C/S/A as adjustable mode and P13 to P24 preset programs only for EV-906A).	Equivalent	The differences are limited to mode naming and program numbering (e.g., EV-906A uses B/N/M/SD1/SD2 and C/S/A modes with 24 programs, while Z4 uses 30 preset programs P1–P30). These changes result from software and interface optimization for OTC use and do not affect the device's intended use, safety, or effectiveness.
Power Source(s)	Rechargeable Li-Polymer battery via USB-C	Rechargeable Li-Polymer battery via USB charging cable	Equivalent	The difference in the new device is limited to the connector type and does not impact the device's safety and effectiveness.
- Method of Line Current Isolation	Type BF	Type BF	Same	--
- Patient Leakage Current(Normal)	Under 0.1	Under 0.1	Same	--
- Patient Leakage Current (Single fault)	Under 0.5	Under 0.5	Same	--

Number of Output Modes	2 output modes: TENS mode and EMS mode	2 output modes: TENS mode and EMS mode	Same	--
Number of Output Channels	4	4	Same	--
- Synchronous or Alternating?	Synchronous	Synchronous	Same	--
- Method of Channel Isolation	Transformer-based or equivalent circuit isolation	Transformer-based or equivalent circuit isolation	Same	--
Regulated Current or Regulated Voltage?	Constant Current	Constant Current	Same	--
Software/Firmware/Microprocessor Control?	Yes	Yes	Same	--
Automatic Overload Trip?	No	No	Same	--
Automatic No-Load Trip?	Yes	Yes	Same	--
Automatic Shut Off?	Yes	Yes	Same	--
Patient Override Control?	No	No	Same	--
Indicator Display: - On/Off Status?	Yes	Yes	Same	--
- Low Battery?	Yes	No	Equivalent	The new device includes a low battery indicator. This difference does not impact the device's safety and effectiveness.
- Voltage/Current Level?	Yes (Intensity)	Yes (Intensity)	Same	--
Timer Range (minutes)	5–60 minutes or continuous mode	5–60 minutes or continuous mode	Same	--
Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	Same	--
Compliance with 21 CFR 898?	Yes	Yes	Same	--

Weight	150 g with battery	250 g with battery	Equivalent	The new device is lighter. This difference does not impact the device's safety and effectiveness.
Dimensions (in.) [W x H x D]	11.8 x 6.0 x 3.1 cm	13.8 x 7.8 x 2.8 cm	Equivalent	The new device has a minor dimensional difference. This difference does not affect the device's safety and effectiveness.
Housing Materials and Construction	ABS, PC, Rubber	ABS, Rubber	Equivalent	The new device includes a polycarbonate (PC) mirror panel. Both the new device and the predicate use biocompatible plastics and the same structure. This difference does not impact the device's safety and effectiveness.

B. TENS Mode Output Specifications

Feature / Characteristic	**New Device: Z4**	**Predicate Device: K201335 (EV-906/EV-906A)**	**Same or Equivalent?**	**Explanation of Differences**
Waveform (e.g., pulsed monophasic, biphasic)	Asymmetrical Bi-Phasic Square Pulse	Pulsed monophasic	Equivalent	The new device uses an asymmetrical biphasic square pulsed waveform, while the predicate device uses a pulsed monophasic waveform. This difference does not impact the device's safety and effectiveness.

Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Same	--
Maximum Output Voltage (Volts) (+/-20 %)		51.6 @500Ω 128.0V @2KΩ 218.0V @10KΩ	51.6 @500Ω 128.0V @2KΩ 218.0V @10KΩ	Same	--
Maximum Output Current (mA) (+/-20 %)		103.2mA @500Ω 64.0mA @2KΩ 21.8mA @10KΩ	103.2mA @500Ω 64.0mA @2KΩ 21.8mA @10KΩ	Same	--
Duration of primary phase (uS)		300 max. (Single phase)	300 max. (Single phase)	Same	--
Pulse Duration (mS)		45 max.	45 max.	Same	--
Frequency (Hz) [or Rate (pps)]		150 max.	150 max.	Same	--
For multiphasic waveforms only:	Symmetrical phases?	No Asymmetrical phases	No Asymmetrical phases	Same	--
Maximum Charge (Microcoulombs per pulse) (if zero, state method of achieving zero net charge for net charge/pulse)		14.97	14.97	Same	--
- Maximum Phase Charge (uC)		6.57	6.57	Same	--

- Maximum Current Density(mA/cm^2)	0.09	0.09	Same	--
- Maximum Average Current (mA)	2.25	2.25	Same	--
- Maximum Average Power Density (mW/cm^2)	0.98	0.98	Same	--
Average DC current through electrodes when device is on but no pulses are being applied (uA)	Not applicable	Not applicable	Same	--
Pulse per burst	9	9	Same	--
Burst per second (Hz)	0.5~5	0.5~5	Same	--
Bust duration (uS)	300	300	Same	--
Duty Cycle	Same for each program	Same for each program	Same	--
Method of achieving zero net charge for net charge/pulse	Monophasic asymmetric wave for each pulse	Monophasic asymmetric wave for each pulse	Same	--

C. EMS Mode Output Specifications

Feature / Characteristic	**New Device: Z4**	**Predicate Device: K201335 (EV-906/EV-906A)**	**Same or Equivalent?**	**Explanation of Differences**
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed monophasic	Pulsed monophasic	Same	--

Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Same	--
Maximum Output Voltage (Volts) (+/-20 %)		50.8@500Ω 127.0V @2KΩ 212.0V @10KΩ	52.0 @500Ω 128.0V @2KΩ 216.0V @10KΩ	Equivalent	Minor variation within ±20% tolerance; no impact on safety or effectiveness
Maximum Output Current (mA) (+/-20 %)		101.6mA @500Ω 63.5mA @2KΩ 21.2mA @10KΩ	104.0mA @500Ω 64.0mA @2KΩ 21.6mA @10KΩ	Equivalent	There is a minor difference in the maximum output current for the new device. This difference does not impact safety and effectiveness.
Duration of primary phase (uS)		300 max. (Single phase)	300 max. (Single phase)	Same	--
Pulse Duration (mS)		45 max.	45 max.	Same	--
Frequency (Hz) [or Rate (pps)]		150 max.	150 max.	Same	--
For multiphasic waveforms only:	Symmetrical phases?	No Asymmetrical phases	No Asymmetrical phases	Same	--
Maximum Charge (Microcoulombs per pulse) (if zero, state method of achieving zero net charge for net charge/pulse)		14.87	15.02	Equivalent	Difference within acceptable range; does not affect safety or effectiveness

- Maximum Phase Charge (uC)		6.47	6.62	Equivalent	This difference does not impact safety and effectiveness
- Maximum Current Density(mA/cm^2)		0.09	0.09	Same	--
- Maximum Average Current (mA)		2.23	2.25	Equivalent	This difference does not impact safety and effectiveness
- Maximum Average Power Density (mW/cm^2)		0.96	0.99	Equivalent	This difference does not impact safety and effectiveness
Burst Mode (i.e. pulse trains)	Pulse per burst	No burst mode	No burst mode	Same	--
	Burst per second				
	Bust duration				
	Duty Cycle				
On Time (Second)		2~99	2~99	Same	--
Off Time (second)		0~99	0~99	Same	--
Ramp Time (second)		1~8 must less than On time	1~8 must less than On time	Same	--

VI.3 Output Safety & Performance Comparison

Based on waveform and Vrms/Arms analysis across different load impedances (500Ω, 2kΩ, 10kΩ), the subject device meets IEC 60601 safety limits and demonstrates equivalent.

- Maximum average current
- Maximum current density
- Maximum power density

Despite minor variations in waveform parameters and program configurations, performance testing and waveform comparisons confirm that these differences do not raise new safety or effectiveness concerns.

VI.4 Conclusion

The subject device Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator is substantially equivalent to the cited predicate device (K201335) in design, function, and safety. All differences, including waveform shape, pulse duration, output values, and interface features, were evaluated through bench testing, waveform analysis, and power/current density calculations. Results confirm that the subject device performs comparably and meets safety standards under normal and worst-case operating conditions.

VII. PERFORMANCE DATA

VII.1 Non-Clinical Tests Performed

Compliance to applicable voluntary standards include: IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices.

VII.2 Clinical Testing

No clinical studies were required or conducted.

VIII. CONCLUSION

The subject device, Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator, has been demonstrated to be substantially equivalent to the cited predicate device (K201335), in terms of intended use, design, technological characteristics, and performance.

From a clinical perspective, both devices are intended for the same over-the-counter (OTC) applications: the temporary relief of pain using TENS programs and the stimulation of healthy muscles using EMS programs. They are intended for use by the same user group, under similar conditions and environments.

From a technical perspective, both devices operate based on similar principles and deliver electrical stimulation via electrodes through pre-programmed waveforms. The differences in waveform configuration, pulse duration, output voltage/current, timer settings, device dimensions, weight, and number of control buttons were carefully evaluated and validated through applicable safety and performance testing, including compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10. These differences were determined to have no impact on the safety or effectiveness of the device.

From a biological perspective, the materials used in patient-contacting components, their surface characteristics, contact duration, and location of contact are identical between the subject and predicate devices. Therefore, no additional biological risk is introduced by the subject device.

In conclusion, the differences in waveform parameters, device dimensions, user interface features, and output specifications do not affect the product's safety or performance. Performance testing has been completed to demonstrate that the subject device, Z4 Li-Battery Powered OTC TENS/EMS Combination Stimulator, is substantially equivalent to the cited predicate device (K201335).