



January 16, 2025

Pepper Interactive Inc
Emilia Von Keyserlingk
Managing Director
251 Little Falls Drive
Wilmington, Delaware 19808-1674

Re: K233770
Trade/Device Name: Pepper EMS Training System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 15, 2023
Received: November 24, 2023

Dear Emilia Von Keyserlingk:

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

for Heather Dean, PhD

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

Submission Number (if known)

K233770

Device Name

Pepper EMS Training System

Indications for Use (Describe)

The Pepper EMS Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Pepper EMS Training System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated.

The Pepper EMS Training System's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

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

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.87(h) and 21 CFR 807.92.

Submitter

Pepper Interactive Inc
251 Little Falls Drive
Wilmington DE, 19808-1674

Contact Person

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Date Summary Prepared

January 13, 2025

Device

Device Trade Name:	Pepper EMS Training System
Device Common Name:	Powered Muscle Stimulator for Muscle Conditioning
Regulation Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850
Regulatory Class:	Class II
Product Code:	NGX
Classification Panel:	89, Physical Medicine

Predicate Device

Device Name:	Katalyst Training System
510(k) Number:	K190966
Regulation Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850

Regulatory Class: Class II

Product Code: NGX

Device Description

The Pepper EMS Training System is a battery powered muscle stimulator that uses electrical muscle stimulation (EMS) technology to stimulate healthy muscles and help to improve muscle performance. Specifically, it uses neuromuscular electrical stimulation (NMES) to stimulate motor nerves, creating a muscle contraction to recruit more muscle fibers while training.

The Pepper EMS Training System is the main part and consists of two separate accessories, the Pepper Suit and the Pepper Battery Box. The Pepper EMS Training System is designed to be used with the Pepper Application, which is the interface between the user and the Battery Box and runs on a user supplied iOS or Android device. The iOS or Android device communicates wirelessly with the Battery Box using Bluetooth 4.2.

Indications for Use

The Pepper EMS Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

The Pepper EMS Training System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated.

The Pepper EMS Training System's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

Comparison to the Predicate Device

The similarities and differences between the technology and specifications of the subject device and its predicate devices are reflected below:

Basic Device Characteristics - Comparison with Predicate Devices

Characteristics	New Device	Predicate Device	Comparison
Manufacturer	Pepper Interactive Inc.	Katalyst Inc.	N/A

Device name, model	Pepper EMS Training System	Katalyst Training System Model 1	N/A
Classification name	Powered muscle stimulator	Powered muscle stimulator	Same
Product code	NGX	NGX	Same
Regulation number	21 CFR 890.5850	21 CFR 890.5850	Same
Panel	Physical Medicine	Physical Medicine	Same
Class	Class II	Class II	Same
510(k) number	K233770	K190966	N/A
Prescription/OTC	OTC	OTC	Same
Indications for use	<p>The Pepper EMS Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Pepper EMS Training System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated. The Pepper EMS Training System's electrical impulses allow the triggering of action potentials</p>	<p>The Katalyst Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Katalyst Training System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated. The Katalyst Training System's electrical impulses allow the triggering of action potentials on motoneurons</p>	Same

	<p>on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.</p>	<p>of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.</p>	
Target population	It is to be used by adults only.	It is to be used by adults only.	Same
Connection of device to electrode	<p>The Pepper EMS Battery Box connects to the Suit through output cables that terminate with pogo pin connectors. The Suit contains embedded cables which make connection with the built-in electrodes.</p>	<p>The Impulse Pack connects to the Suit through output cables that terminate with pogo pin connectors. The Suit contains an embedded cable harness which makes connection with the built-in electrodes.</p>	<p>Different</p> <p>The Pepper EMS Training System contains a one-piece suit and does not need extra connectors like the predicate device. Both devices connect their accessories, suit and battery box, via pogo pins. This does not affect safety and effectiveness of the subject device.</p>

	Neither the cables nor the electrodes are removable.	Neither the cable harness or the electrodes are removable. The Suit also features leads with snap connectors for connecting to the arm electrodes.	
Power source(s)	Lithium Polymer (Li-Po) rechargeable battery 3,8 V, 2,650 mAh	Lithium Polymer (Li-Po) rechargeable battery 7.4V, 2,050 mAh	Different The Pepper battery has a lower voltage and higher capacity to improve efficiency and longevity.
Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	Same
Patient leakage current	N/A (battery operated device)	N/A (battery operated device)	Same
Normal condition	N/A (battery operated device)	N/A (battery operated device)	Same
Single fault condition	N/A (battery operated device)	N/A (battery operated device)	Same
Number of output modes	One (NMES)	One (NMES)	Same
Number of output channels	16	13	Different Three extra channels, all channels are identical and conforming to regulations.
-Synchronous or alternating?	Synchronous, but never 2 channels activated at the same time	Synchronous, but never 2 channels activated at the same time	Same
-Method of channel isolation	Multi-Channel High Voltage Analog Switches. Except during channel activation, each channel is always in high Z state.	Multi-Channel High Voltage Analog Switches. Except during channel activation, each channel is always in high Z state.	Same

Regulated current or regulated voltage?	Regulated current (all channels)	Regulated current (all channels)	Same
Software/firmware/microprocessor control?	Yes	Yes	Same
Automatic overload trip?	Yes	Yes	Same
Automatic no-load trip?	Yes	Yes	Same
Automatic shut off?	„On/Off“ switch	„On/Off“ switch	Same
Patient override control?	Yes	Yes	Same
Indicator display - on/off status?	Yes	Yes	Same
-Low battery?	Yes	Yes	Same
-Voltage/current level?	Yes	Yes	Same
Timer range (minutes)	Maximum program: 25 minutes	Maximum program: 60 minutes	Different The maximum program length of the subject device is more restricted than that of the predicate device.
Compliance with voluntary standards?	Yes IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11	Yes IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Different The subject device is additionally compliant to IEC 60601-1-11.
Compliance with 21 cfr 898?	Yes	Yes	Same
Weight	Battery Box – 152 g	Impulse Pack - 248 g	Different Pepper’s battery box is smaller and therefore also lighter than the predicate’s impulse pack.
Dimensions	Impulse Pack -102 x 22mm	Impulse Pack – 148x78 mm Connector 1 – 65x32mm Connector 2 – 56x32mm	Different Pepper’s battery box is smaller than the predicate’s impulse pack and doesn’t have additional connectors.
Housing material and construction	Plastic injection molding	Plastic injection molding	Same

Output Specification - Comparison with Predicate Devices

Characteristic	New Device	Predicate Device	Comparison
Manufacturer	Pepper Interactive Inc	Katalyst Inc	N/A
Device name, model	Pepper EMS Training System	Katalyst Trainings System	N/A
Waveform	Cardio: Symmetrical Biphasic Strength: Symmetrical Biphasic Relax: Symmetrical Biphasic	Endurance: Symmetrical Biphasic Resistance: Symmetrical Biphasic Strength: Symmetrical Biphasic Explosive Strength: Symmetrical Biphasic Potentiation: Symmetrical Biphasic Training Recovery : Symmetrical Biphasic Competition Recovery: Symmetrical Biphasic Warmup: Symmetrical Biphasic Muscle Relaxation: Symmetrical Biphasic	Same The waveforms of the subject and predicate are the same. The subject device offers only three training programs: Cardio, Strength and Relax. The training programs of the subject device are part of the range of training programs of the predicate device.
Shape	Cardio: Rectangular Strength: Rectangular Relax: Rectangular	Endurance: Rectangular Resistance: Rectangular Strength: Rectangular Explosive Strength: Rectangular Potentiation: Rectangular Training Recovery :	Same

		<p>Rectangular Competition Recovery: Rectangular Warmup: Rectangular Muscle Relaxation: Rectangular</p>	
<p>Maximum output voltage (+/-10%)</p>	<p>Cardio: 50 V @ 500 Ω 50 V @ 2 kΩ 50 V @ 10 kΩ Strength: 54 V @ 500 Ω 53 V @ 2 kΩ 51 V @ 10 kΩ Relax: 51 V @ 500 Ω 52 V @ 2 kΩ 51 V @ 10 kΩ</p>	<p>Endurance: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Resistance: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Strength: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Explosive Strength: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Potentiation: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Training Recovery : 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Competition Recovery: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Warmup: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ Muscle Relaxation: 60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ</p>	<p>Different</p> <p>The Pepper EMS Training System's maximum voltage is less than that of the predicate device.</p>
<p>Maximum output current (+/-10%)</p>	<p>Cardio: 100 mA @ 500Ω</p>	<p>Endurance: 120 mA @ 500 Ω</p>	<p>Different</p>

	<p>25mA @ 2kΩ 5mA @ 10kΩ Strength: 108 mA @ 500Ω 27mA @ 2kΩ 5mA @ 10kΩ Relax: 102 mA @ 500Ω 26mA @ 2kΩ 5mA @ 10kΩ</p>	<p>50 mA @ 2 kΩ 10 mA @ 10 kΩ Resistance: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Strength: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Explosive Strength: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Potentiation: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Training Recovery : 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Competition Recovery: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Warmup: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ Muscle Relaxation: 120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ</p>	<p>The Pepper EMS Training System’s maximum current is less than that of the predicate devices.</p>
<p>Pulse width</p>	<p>Cardio: 160 to 490 μs Strength: 160 to 490 μs Relax: 160 to 490 μs</p>	<p>Potentiation: 250 to 375 μs Endurance: 250 to 375 μs Resistance: 250 to 375 μs Strength: 250 to 375 μs Explosive Strength: 250 to 375 μs Training Recovery:</p>	<p>Different</p> <p>The subject device provides customization through a wider spectrum of pulse width. The main output parameters (output current and output voltage) and energy density are lower for the subject devices than for the predicate device, which complies with IEC 60601-2-10 limits.</p>

		250 to 375 μ s Competition Recovery: 250 to 375 μ s Warmup: 250 to 375 μ s Muscle Relaxation: 250 to 375 μ s	
Frequency	Cardio: 15 Hz Strength: 85 Hz Relax: 100 Hz	Endurance: 10 Hz Resistance: 50 Hz Strength: 75 Hz Explosive Strength: 105 Hz Potentiation: 1 to 75 Hz Training Recovery : 1 to 9 Hz Competition Recovery: 1 to 6 Hz Warmup: 5 Hz Muscle Relaxation: 1 Hz	Different The Pepper EMS Training System's frequency range (15-100Hz) is a subset of that of the predicate device: 1-105Hz.
Phase duration	160 to 490 μ s	250 to 375 μ s	Different The phase duration of Pepper EMS Training System is wider than predicate device. The main output parameters (output current and output voltage) and energy density are lower for the subject devices than for the predicate device, which complies with IEC 60601-2-10 limits.
Net charge	Cardio: 0 μ C @ 500 Ω Strength: 0 μ C @ 500 Ω Relax: 0 μ C @ 500 Ω	Endurance: 0 μ C @ 500 Ω Resistance: 0 μ C @ 500 Ω Strength: 0 μ C @ 500 Ω Explosive Strength:	Same

		<p>0 μC @ 500 Ω Potentiation: 0 μC @ 500s Ω Training Recovery : 0 μC @ 500 Ω Competition Recovery: 0 μC @ 500 Ω Warmup: 0 μC @ 500 Ω Muscle Relaxation: 0 μC @ 500 Ω</p>	
Maximum phase charge	53 μC @ 500 Ω	45 μC @ 500 Ω	<p>Different</p> <p>Maximum phase charge of Pepper EMS Training System is higher than predicate device. The main output parameters (output current and output voltage) and energy density are lower for the subject devices than for the predicate device, which complies with IEC 60601-2-10 limits.</p>
Maximum current (rms) density	0.9 mA/cm ² @ 500 Ω	1.15 mA/cm ² @ 500 Ω	<p>Different</p> <p>Subject device has a lower maximum current density than the predicate due to the lower maximum current, which complies with the IEC 60601-2-10 limits.</p>
Maximum Power Density (using smallest electrode conductive surface area)	16.95 mW/cm ² @ 500 Ω	22.68 mW/cm ² @ 500 Ω	<p>Different</p> <p>Subject device has a lower maximum current density than the predicate due to the lower maximum current and output voltage.</p>
Pulses per burst	4 – 400	4 – 420	<p>Different</p> <p>The pulses per burst of the subject device are slightly lower than the pulses per burst of the predicate device. This does not raise any concerns.</p>
Bursts per second	0.125	0.125	Same
Burst duration (seconds)	4	4	Same

Duty Cycle	50%	50%	Same
ON time (seconds)	4	4	Same
OFF time (seconds)	4	4	Same

Discussion

The predicate device Katalyst Training System Model 1 is currently marketed in the US and approved by the FDA with the 510(k) number K190966. The comparison tables above show similarities and differences between the subject and the predicate device according to the Guidance Document for Powered Muscle Stimulator 510(k)s, which will be discussed in the following.

Indications for use and the target population of the Pepper EMS Training System and the Katalyst Training System are identical. In addition to some general characteristics which are identical, output specifications, like waveform, shape, net charge, burst duration and duty cycles are identical. These are the differences which could be observed:

- The Pepper EMS Training System contains a one-piece suit with embedded cables which connect the built-in electrodes whereas the Katalyst Training System uses different pieces and snap connectors which have to be connected before use. Both devices connect their suit and battery box via pogo pins. The composition of the Systems affects the amount of pieces and setup steps but has no effects on the treatment. Similar to the predicate device, the subject's skin contacting materials have been tested to ISO 10993-5 and ISO 10993-10 standard under GLP
- The Pepper Battery Box uses a lower voltage and a higher capacity than the Katalyst Impulse Pack. This affects the efficiency and longevity of the battery box but has no effects on the treatment or battery safety. Cells comply with IEC 62133-2 "Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems".
- The Pepper EMS Training System and the Katalyst Training System both have one output mode. The Pepper EMS Training System has three additional output channels, 16 compared to 13. This allows for the treatment of more muscle groups; all channels have the same technical characteristics and comply with IEC 60601-2-10.
- The Pepper EMS Training System has a shorter and therefore more restricted maximum program length than that of the predicate device which raises no concerns regarding safety and effectiveness.
- The Pepper EMS Training System is additionally compliant to IEC 60601-1-11.
- The Pepper Battery Box is smaller and therefore also lighter than the predicate's Impulse Pack, and doesn't have any additional connectors. The Pepper Battery Box measures 102 x 22mm and weighs 152g, whereas the Katalyst Impulse Pack measures 148 x 78mm plus two connectors and weighs 248g. This does not affect the treatment or battery safety as the cells comply with IEC 62133-2

- The waveforms and shape of the subject and predicate device are the same. The subject device only offers three training programs: Cardio, Strength and Relax. The training programs of the subject device are a subset of the predicate's training programs which raises no concerns regarding safety and effectiveness.
- The Pepper EMS Training System has a lower maximum output voltage, current and frequency. This does not raise any concerns which raises no concerns regarding safety and effectiveness and complies with IEC 60601-2-10 limits.
- The Pepper EMS Training System has a wider pulse width range, phase duration and maximum phase charge than the predicate device which allows customization. The main output parameters, current, voltage and density, are lower for the subject device than for the predicate device, which complies with IEC 60601-2-10 limits.
- The Pepper EMS Training System has a lower maximum current and maximum power density than the predicate device due to the lower maximum current and output voltage. This does not raise any concerns.
- The subject device's pulses per burst are 4-400 and therefore slightly lower than of the predicate device with 4-420. This does not raise any concerns.

As these minor differences don't affect the basic safety of the device or create any significant deviation in performance from the predicate devices and given that both devices comply to the same main standards, the Pepper EMS Training System can be considered substantially equivalent to the predicate device Katalyst Training System. This is also supported by the tests according to IEC 60601 1:2005+ A1:2012+ A2:2020.

Standards

In order to ensure adequate performance and safety of the Pepper EMS Training System, it has been designed and manufactured in accordance with the following standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1, Mod.)
- IEC 60601-1-2 Edition 4.0 2014-02 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 Edition 2.1 2016-04 Medical Electrical Equipment - Part 2-10: Particular Requirements for The Basic Safety and Essential Performance of Nerve and Muscle Stimulators
- IEC 62133 Edition 2.0 2012-12 Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes - Safety Requirements for Portable Sealed Secondary Cells, And for Batteries Made from Them, For Use in Portable Applications [Including: Corrigendum 1 (2013)]
- ISO 14971 Second Edition 2007-03-01 Medical Devices - Application of Risk Management to Medical Devices

- ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- AAMI /ANSI /IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]
- IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Non-Clinical Testing

The Pepper EMS Training System was subjected to testing in accordance with the appropriate standards and the results are provided in this 510(k). The non-clinical tests performed are as follows:

- **Biocompatibility Testing**

The Skin contacting materials have been tested to ISO 10993-5 and ISO 10993-10 standard under GLP.

- **Software Verification and Validation**

The Battery Box firmware and Pepper Application were verified in accordance with the requirements of FDA's guidance document: General Principles of Software Validation. This testing proves that all software requirement specifications were met.

- **Battery Testing**

The Lithium-Polymer battery used in the Battery Box was tested by the battery manufacturer for compliance with IEC 62133.

- **Engineering Bench Testing**

In addition to the full system validation testing, the 510(k) also included testing in accordance with the recommendations of FDA's "Guidance Document for Powered Muscle Stimulator 510(k)s" issued on June 9, 1999.

- **Electrical Safety and Electromagnetic Compatibility:**

The Pepper EMS Training System has been tested to AAMI/ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-2-10.

- **Wireless Coexistence Testing:**

The performance of the Pepper EMS Training System was evaluated in an environment with other Pepper EMS Training Systems and with other types of 2.4 GHz wireless devices (Bluetooth and Wi-Fi). The device met all specified requirements.

Clinical Testing

No clinical studies are submitted to support this premarket notification submission.

Conclusion

Test results demonstrate the Pepper EMS Training System is substantially equivalent to the predicate device.