September 18, 2019

Dongguan Yingfeng Metal & Plastic Products Co., Ltd
% Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg.1, Southward Ruifeng Business Center
Guimiao Road
Shenzhen, 518000 CN

Re: K183103
Trade/Device Name: EMS Belt (Model: MC0485)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 14, 2019
Received: August 15, 2019

Dear Rain Yip:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Vivek Pinto, PhD
Director (Acting)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183103

Device Name
EMS Belt (Model MC0485)

Indications for Use *(Describe)*
To be used to stimulate healthy muscles in order to improve and 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.

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510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: 2018-10-26

I. Submitter

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II. Device

Name of Device/Model: EMS Belt/MC0485
Common or Usual Name: Powered muscle stimulator
Classification Name: Stimulator, Muscle, Powered, For muscle conditioning
Regulatory Class: II
Product Code: NGX
Regulation Number: 21 CFR 890.5850

III. Predicate Device

The predicate devices are listed as below:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Hivox Biotek Inc.	(Primary) HIVOX OTC Electrical Stimulator/SEM44	K171803	Nov. 29, 2017
Shenzhen OSTO Technology Company Limited	Health Expert Electronic Stimulator/AST-300C and AST-300D	K133929	Nov. 12, 2014
Actegy, Ltd	Revitive IX (OTC)/RIX	K143207	Mar. 23, 2015

Reference device(s):

Manufacturer	Reference Device	510(k) Number	Approval Date

Manufacturer	Reference Device	510(k) Number	Approval Date
EasyMed Instruments Co., Ltd.	SmartTENS	K143430	May 29, 2015

IV. Device Description

MC0485 EMS Belt is a one channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It is comprised of an electronic stimulator module for signal generation, a belt for fixation, and four electrode pads for signal connection to skin. The built-in electrode pads are located on the inner surface of the belt.

Power is derived from 3 batteries located in a compartment protected by a removable battery cover for the EMS Belt. There is no current passed from side to side. The user cannot access the wiring or connectors within the belt.

The stimulator sends gentle electrical current to targeted muscle area through the electrode pads placed on the skin. The parameters of the EMS Belt are controlled by the buttons on the controller and are displayed by the LCD on the controller. Its intensity level can be adjustable by user.

V. Indications for Use

To be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

VI. Comparison of Technological Characteristics With the Predicate Device

The EMS Belt is substantially equivalent to the predicated device based on intended use, design, specifications and performance. It raises no safety or efficacy concerns when compared to the predicate devices.
Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicates is provided below:

Comparison Elements	**Subject Device**	**Primary Predicate Device K171803**	**Predicate Device K133929**	**Predicate Device K143207**	**Reference Device K143430**	**SE**
Trade Name/Model	EMS Belt/MC0485	HIVOX OTC Electrical Stimulator/SEM44	Health Expert Electronic Stimulator/AST-300C and AST-300D	Revitive IX (OTC)/RIX	SmartTENS	/
510(k) Number	To be assigned	K171803	K133929	K143207	K143430	/
Regulation Number	21CFR 890.5850	21CFR 882.5890	21CFR 882.5890	21CFR 882.5890	21CFR 882.5890	SE
Device Class	II	II	II	II	II	SE
Product Code	NGX	NUH, NGX	NUH, NGX	NUH, NGX	NUH	SE NOTE 1
Indication for Use/Intended Use	To be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	SEM44 (EMS): The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance. SEM44 (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.	PMS (Mode 1~8): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 9~25): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	To temporarily increase local blood circulation in healthy leg muscles To stimulate healthy muscles in order to improve and facilitate muscle performance. For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties	The device is intended for the relief of pain associated with sore or aching muscles of the low back, arms, or legs due to stain from exercise or normal household and work activities.	SE NOTE 1

Comparison Elements		**Subject Device**	**Primary Predicate Device K171803**	**Predicate Device K133929**	**Predicate Device K143207**	**Reference Device K143430**	**SE**
Location for Use		OTC	OTC	OTC	OTC	OTC	SE
Basic Specifications							
Power Supply		4.5V (3 × 1.5V Alkaline batteries)	4.5V (batteries, 3×1.5V AAA)	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	Power adaptor Input: 100-240V, 50/60Hz, 0.18A Output: 5.0VDC, 1.0A	3.7V rechargeable lithium battery	SE NOTE 2
Method of Line Current Isolation		N/A	N/A	Type BF Applied Part	Not publicly available	Not publicly available	SE
Patient Leakage Current	Normal Condition	N/A	N/A	AC: 54.5μA, DC: 0.5μA	Not publicly available	Not publicly available	SE
	Signal Fault Condition	N/A	N/A	AC: 120.0μA, DC: 0.6μA	Not publicly available	Not publicly available	SE
Number of Output Modes		10	EMS: 35 TENS: 15	25	1	7	SE NOTE 2
Number of Output Channels		1	2	2	2 (1 for foot, 1 for body pads)	1	SE NOTE 2
Synchronous or Alternating?		Alternating	Synchronous	Synchronous	Not publicly available	Not publicly available	SE
Method of Channel Isolation		N/A	By electrical circuit and software	Voltage Transform Isolation "BODY▼" and "BODY▼" buttons for body channel, "SOLE▲" and "SOLE▼"	Not publicly available	Not publicly available	SE

Comparison Elements		**Subject Device**	**Primary Predicate Device K171803**	**Predicate Device K133929**	**Predicate Device K143207**	**Reference Device K143430**	**SE**
				buttons for feet channel			
Software /Firmware /Microprocessor Control?		Yes	Yes	Yes	Yes	Yes	SE
Automatic Overload Trip?		No	Yes	No	Yes	Yes	SE
Automatic No-Load Trip?		No	Yes	No	Not publicly available	Yes	SE
Automatic Shut OFF?		Yes	Yes	Yes	Yes	Yes	SE
Patient Override Control?		Yes	Yes	Yes	Yes	Yes	SE
Indicator Display	On/Off Status?	Yes	Yes	Yes	Not publicly available	Yes	SE
	Low Battery?	Yes	Yes	No	Not publicly available	Yes	SE
	Voltage/Current Level?	Yes	Yes	Yes	Not publicly available	Yes	SE
Timer Range		5min, 10min, 15min, 20min, 25min, 30min	5~100minutes	25minutes	1~60minutes	20min, 25min, 30min, 40min depending on preset program	SE NOTE 2
Compliance with Voluntary Standards?		IEC60601-1-2 IEC60601-1	IEC60601-1-2 IEC60601-1	IEC60601-1-2 IEC60601-1	IEC60601-1-2 IEC60601-1	IEC60601-1-2 IEC60601-1	SE

Comparison Elements	**Subject Device**	**Primary Predicate Device K171803**	**Predicate Device K133929**	**Predicate Device K143207**	**Reference Device K143430**	**SE**
	IEC60601-11 IEC60601-2-10 ISO10993-5/10	IEC60601-2-10 ISO10993-5/10	IEC60601-2-10 ISO10993-5/10	IEC60601-2-10 ISO10993-5/10	IEC60601-2-10 ISO10993-5/10	
Compliance with 21CFR898	Yes	Yes	Yes	Yes	Yes	SE
Weight	310 g (without batteries)	89g (including belt clip, without batteries) 123g (including belt clip, and batteries)	2kg (without accessories)	1725g (Without PSU)	64g	SE NOTE 3
Dimensions	78 x 140 x 30mm (controller) 430 x 150 x 12mm (belt)	132 x 63 x 29.5mm(including belt clip)	428 x 428.8 x 185mm	φ360 x 75mm	155.4x 64.4x 19.1mm	SE NOTE 3
Housing Materials and Construction	Controller body: ABS plastic Belt: Mutispandex Electrode pads: TPE	ABS plastic	ABS plastic	Casing/body ABS, footpads NBR	ABS & TPE	SE NOTE 4
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10.	SE
Output Specifications						
Waveform	Symmetrical rectangular	Biphasic, square	Pulsed symmetrical, biphasic, rectangular, with interphase interval	Pulsed symmetrical, rectangular	Biphasic rectangular Monophasic rectangular	SE NOTE 5
Maximum @500Ω	35±10%	100±10% (50±10%(Vp))	44±10%	Foot: 20	68	SE

Comparison Elements		**Subject Device**	**Primary Predicate Device K171803**	**Predicate Device K133929**	**Predicate Device K143207**	**Reference Device K143430**	**SE**
Output Voltage (Volts, Vp)					Body: 32		NOTE 5
	@2kΩ	76V ±10%	180 ±10% (90 ±10%(Vp))	80V ±10%	Foot: 95 Body: 118	102	
	@10kΩ	145V ±10%	250 ±10% (125 ±10%(Vp))	112V ±10%	Foot: 138 Body: 169	110	
Maximum Output Current (mA)	@500Ω	70 ±10%	200 ±10% (100 ±10%(Ip))	88 ±10%	Foot: 40 Body: 64	133	SE NOTE 5
	@2kΩ	37.5 ±10%	90 ±10% (45 ±10%(Ip))	40 ±10%	Foot: 48 Body: 59	51	
	@10kΩ	14.5 ±10%	25 ±10% (12.5 ±10%(Ip))	11.2 ±10%	Foot: 14 Body: 17	11	
Pulse Width		270µs	50-450µs	120µs	Foot: 4-7.5µs Body: 1.4-33.6µs	50-250µs	SE NOTE 5
Frequency (Hz)		1-22Hz	1-150Hz	77.3Hz	Foot: 20-53Hz Body: 35-46Hz	1-150Hz	SE NOTE 5
For Interferential modes only: - Beat Frequency(Hz)		N/A	N/A	Not publicly available	Not publicly available	Not publicly available	SE
For Multiphase waveforms only	Symmetrical Phases?	Yes	N/A	Not publicly available	Not publicly available	Not publicly available	SE
	Phase	N/A	N/A	Not publicly available	Not publicly available	Not publicly available	SE

Comparison Elements		**Subject Device**	**Primary Predicate Device K171803**	**Predicate Device K133929**	**Predicate Device K143207**	**Reference Device K143430**	**SE**
	Duration						
Maximum Phase Charge (μC) @500Ω		23.52	0.045	12.78	Foot: 41 Body: 15	20.01	SE NOTE 5
Maximum Current Density (mA/cm^2) @500Ω		0.13	0.667	0.235	Foot: 0.023 Body: 0.082	0.066	SE NOTE 5
Maximum Power Density (W/cm^2) @500Ω		0.0004	0.0046 (average)	1.38	Foot: 0.55 Body: 1.64	2.66 (average)	SE NOTE 5
Burst Mode	Pulses per burst	1	3	Not publicly available	Foot: 11-256 Body: 49-154	Not publicly available	SE
	Bursts per second	1/22Hz	2/60Hz	Not publicly available	Foot: 0.1-0.5 Body: 0.2-0.5	Not publicly available	SE
	Burst duration (seconds)	0.27ms	36ms	Not publicly available	Foot: 1.9-8.4s Body: 1.9-6.5s	Not publicly available	SE
	Duty Cycle [Line(b) x Line (c)]	N/A	36ms/390ms	Not publicly available	Foot: 0.56-0.87 Body: 0.66-0.87	Not publicly available	SE
ON Time (seconds)		1s	2s	0.6s	Foot: 1.92-8.34s Body: 1.92-6.52s	Not publicly available	SE
OFF Time (seconds)		3s	2s	0.6s	Foot: 1-1.5s Body: 1s	Not publicly available	SE

Comparison in details:

NOTE 1: The "Intended Use" of the subject device is the same as the predicate device K171803 SEM44's EMS mode and K133929's PMS (mode 1~8), as well as is within the predicate device K143207. Meanwhile, the "Product Code" of the subject device is within the predicate devices, and these kinds of powered muscle stimulator are classified as NGX in accordance with FDA regulation. This define does not affect the intended use or normal use of the subject device.

NOTE 2: Although the "Power Supply", "Number of Output Modes", "Number of Output Channels", and "Timer Range" of the subject device are a little different from the predicate devices, these differences do not raise new questions of safety and effectiveness.

NOTE 3: Although the "Weight" and "Dimensions" of the subject device are different from the predicate devices, these differences are insignificant in the terms of safety or effectiveness.

NOTE 4: The "Housing Materials and Construction" (materials of skin-contacting components) of the enclosure of the subject device is consistent completely with the predicate devices, and the material of the electrodes is TPE (Thermo-Plastic Elastomers), which is consistent with the electrodes used by K143430. Although their supplier is not sure, they all comply with the requirements of ISO 10993-1 and have been tested and passed the cytotoxicity test, skin sensitization test, and irritation test. So these differences will not raise any safety or effectiveness issue.

NOTE 5: Although the "Maximum Output Voltage", "Maximum Output Current", "Pulse Duration", "Frequency", "Maximum Phase Charge", "Maximum Current Density", and "Maximum Power Density" of the subject device are a little different from the predicate devices, they all comply with the requirements of IEC 60601-1 and IEC 60601-2-10 standard, as well as the Guidance for Powered Muscle Stimulator for Muscle Conditioning. So these differences will not raise any safety or effectiveness issue.

CONCLUSION: The subject device is substantially equivalent to the predicate devices.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the EMS Belt was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on June 16, 2016", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity

- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) EMC and Electrical Safety

EMC and Electrical safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: 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
- IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

3) Software Verification and Validation

Software documentation consistent with ***moderate level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

4) Other Performance Verification

- The Electrode Pad Performance Test Report has been conducted to verify the current dispersion and shelf-life of the electrodes used by the subject device in the expiration date according to the requirements of the FDA Guidance –Shelf Life of Medical Device and ASTM F1980-07 Standard.
- The waveform and output test report has also been conducted to verify the output specifications of the subject device according to the FDA Guidance for Powered Muscle Stimulator 510(k)s.

Summary

Based on the above performance as documented in this application, EMS Belt was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

The subject device EMS Belt is to be concluded substantial equivalent to its predicate devices.