February 12, 2019

Medical Cables, S.L.
José Fuertes Peña
Manager
Duque de la Victoria 6, 1°
Malaga, Spain 29015

Re: K181955
Trade/Device Name: WIEMSPRO
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 18, 2018
Received: January 16, 2019

Dear José Fuertes Peña:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181955

Device Name
WIEMSPRO

Indications for Use *(Describe)*
WIEMSPRO is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The WIEMSPRO is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of WIEMSPRO training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

WIEMSPRO is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes.

WIEMSPRO electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones 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.

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medicalcables	510(k) Premarket Notification	WIEMS$_{PRO}$

DATE OF SUBMISSION: 2018-03-02

SUBMITTER NAME: Medical Cables, S.L.
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DEVICE TRADE NAME: WIEMS$_{PRO}$
COMMON NAME: Powered muscle stimulator.
CLASSIFICATION NAME: Stimulator, Muscle, Powered, For Muscle Conditioning (21 CFR 890.5850)

PREDICATE DEVICE(S): E-Fit EF-1280 (K133225)
Compex Wireless USA (K170903)

DEVICE DESCRIPTION:

The device described in this submission is an electro-medical device intended for stimulating healthy muscles in order to improve or facilitate muscle performance. It is designed for personal training performances.

WIEMS$_{PRO}$ is a device with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes. The device must be used over user's cotton undergarments and is therefore not patient-contacting

WIEMS$_{PRO}$ system cannot be used while the user is in motion or lifting weights.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, the WIEMS$_{PRO}$ device is compared with the following previously cleared devices:

- E-Fit EF-1280 (K133225)
- Compex WirelessUSA (K170903)

Comparison of the proposed devices with the predicate devices is summarized in the following table:

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	**PROPOSED DEVICE** WIEMS$_{PRO}$	**PREDICATE DEVICE** E-Fit EF-1280	**PREDICATE DEVICE** Compex Wireless USA	**Comparison**
GENERAL COMPARISON				
Classification name	Powered muscle stimulator	Powered muscle stimulator	Powered muscle stimulator	Same
Product code	NGX	NGX	NGX	Same
Regulation number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	Same
Panel	Physical Medicine	Physical Medicine	Physical Medicine	Same
Class	Class II	Class II	Class II	Same
510(K) Number	--	K133225	K170903	N/A
INTENDED USE				
Indication for use	WIEMS$_{PRO}$ is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The WIEMS$_{PRO}$ is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of WIEMS$_{PRO}$ training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. WIEMS$_{PRO}$ is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes. WIEMS$_{PRO}$ electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones 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	E-fit EF-1280 is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes. The E-Fit EF-1280 intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit EF-1280 is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the E-Fit EF-1280 training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The E-Fit EF-1280 electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor	The Compex Wireless USA 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 Compex Wireless USA is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is contraindicated. The work imposed on the muscles by the Compex Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones 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. The Compex Wireless USA may therefore be considered a technique of muscle training.	Same WIEMS$_{PRO}$ does not include TENS

	can be imposed on the stimulated muscles.	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. The various types of muscle work that the E-Fit EF-1280 can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit EF-1280 may therefore be considered a technique of muscle training.	The Compex Wireless USA TENS is used for: • temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. • the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	
Intended use	Must be used for only healthy muscles and client. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. It is designed to be used together with a WIEMS$_{PRO}$ Mobile Application.	Must be used for only healthy muscles and client. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.	Must be used for only healthy muscles and client. It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.	Similar. Difference is the software application which controls the device
TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE				
Powered Muscle Stimulator	YES	YES	YES	Same
Power Source	Battery: 3.7 V – 2,4AH (LiPo)	12V (3,4Ah) lead Acid	Remote: : Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 1500[mAh Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 450[mAh]	Similar
Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Same
Patient leakage current **-Normal condition** **-Single fault condition**	N/A (battery operated device) N/A (battery operated device)	N/A (battery operated device) N/A (battery operated device)	N/A (battery operated device) N/A (battery operated device)	Same
Battery operated	YES	YES	YES	Same
Number of output modes	One output mode, but with varying stimulation frequency	One output mode, but with varying stimulation	Two (NMES/TENS)	Similar as Efit

	and duty cycle ranges.	frequency and duty cycle ranges		Different than Compex WIEMS$_{PRO}$ does not include TENS
Regulated current or regulated voltage?	YES, regulated current	YES, regulated current	YES, regulated current	Same
Software/Firmware/Microprocessor Control?	YES	YES	YES	Similar as Efit Similar as Compex
Automatic Overload Trip?	YES	YES	YES	Similar as Efit Similar as Compex
Automatic No-Load Trip?	YES	YES	YES	Similar as Efit Similar as Compex
Automatic Shut Off?	On/Off switch	On/Off switch	On/Off switch	Same as Efit Same as Compex
Patient Override Control?	Yes, push on On/Off button directly pause the program	Yes, push on On/Off button directly pause the program	Yes, push on On/Off button directly pause the program	Same as Efit Same as Compex
Indicator display	Yes	Yes	Yes	Same as Efit Same as Compex
Device weight	300 g	N/A	Remote: 110 [g] - Stimulation Module:2x60 [g] - Docking Station 800 [g]	Similar as Compex
Dimensions (in.) [W x H x D]	[6,66 x 3,27 x 1,18] in	Not available	Not available	Similar as Compex No exact information available

				from predicate devices but not relevant for SE determination
Waveform (e.g., pulsed monophasic, biphasic) (program per program)	Symmetrical biphasic (all programs)	Symmetric Biphasic (all programs)	-Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength : Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Training Recovery (same as Active Recovery): Symmetrical Biphasic -Competition Recovery (same as Recovery Plus): Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Muscle Relaxation (same as Massage): Symmetrical Biphasic -Pain relief TENS (same as FM): Balanced, asymmetrical Biphasic	Similar as Efit Similar as Compex No TENS included in the WIEMS$_{PRO}$ device
Number of programs	20	5+5	22	Different than Efit Similar as Compex
Current / Voltage	125mA/62.5V	72mA/36V	116mA/60V	Similar
Plastic Housing Materials	PLASTIC	STAINLESS STEEL	PLASTIC	Different than Efit Similar as Compex The housing is not in direct contact with the client as used over sportswear
Maximum output voltage	170V	66V-100V	165V	Similar
Maximum output current	125mA	72mA	116mA	Similar
Maximum power	9,61mW/cm^2@500ohm	6,3mW/cm^2 @500ohm	10,2mW/cm^2 @500ohm	Similar

density				
Maximum current density	1,92mA/cm^2 Smallest electrode size: 65 cm ^{2}	0,85mA/cm^2	3,84mA/cm^2 Smallest electrode size: 25 cm ^{2}	Similar
Number of Output channels	1 CHANNEL	1 CHANNEL	4 CHANNELS	Same as Efit
Independent channels with possibility to regulate the current individually	10 CHANNELS	12 CHANNELS	4 CHANNELS	Similar as Efit Different than Compex WIEMS$_{PRO}$ only 1 channel
Pulse duration (width)	100-400usec	100-500usec	200 or 400usec	Similar
Frequency	1-100 HZ	5-120 HZ	1-120 HZ	Similar
Reusable pads	YES	YES	NO	Same as Efit Different than Compex
Compliance with voluntary standards / LAB tests performed	IEC 60601-1-2:2007 IEC 60601-1-6:2010 IEC 60601-2-10:2012 FCC 47 CFR Part 15 IEC 62304:2006 ISO 14971:2007 ANSI/AAMI ES60601-1: 2005 / A2:2010	IEC 60601-1-2:2007 IEC 60601-1-11:2010 IEC 60601-2-10:2012 ISO 14971:2007	IEC 60601-1-2:2007 IEC 60601-1-6:2013 IEC 60601-1-11:2010 IEC 60601-2-10:2012 IEC 62304:2006 ISO 14971:2007	Similar as Efit and Compex The collateral standard IEC 60601-1-11 is not applied in WIEMS$_{PRO}$ device

Maximum output current value is higher in the WIEMS$_{PRO}$ device: 125 mA compared to 72 mA (E-fit) and 116 mA (Compex Wireless USA), however maximum output current density for the WIEMS$_{PRO}$ device is of 1,92 mA/cm^2 much lower than that of Compex Wireless USA (3,84mA/cm^2).
Also, upon analysis of the comparison of the different characteristics presented in the table above, none of the differences spotted impact the equivalence of the subject device when compared to the predicate devices.

INTENDED USE:
As established in the Indications for Use Statement:

> WIEMS$_{PRO}$ intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The WIEMS$_{PRO}$ is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the WIEMS$_{PRO}$ training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.
>
> WIEMS$_{PRO}$ is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes.
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> WIEMS$_{PRO}$ electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones 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.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a wireless electro muscle stimulation device for fitness.

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use, specifically including:

- Electrical safety (including particular requirements for the basic safety and essential performance of nerve and muscle stimulator and for medical electrical equipment)
- Electromagnetic compatibility
- FCC Radio Frequency Testing The WiEMSpro device was tested to FCC requirements and found to comply with the requirements of 47 CFR Part 15 §15.107 and §15.109.

The new device is designed and manufactured in accordance with the following standards:

- IEC 60601-1-2:2007
- IEC 60601-2-10:2012
- IEC 60601-1-6 Edition 3.1 2013-10

- ISO 14971 Second Edition 2007-03-01
- EN ISO 13485:2003 /AC2009
- IEC 62304:2006
- ANSI/AAMI ES60601-1: 2005 / A2:2010

SUMMARY DISCUSSION OF CLINICAL DATA:
Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence. No clinical studies are submitted.

CONCLUSIONS:
We believe the intended use, the indications for use and principle of operation of WIEMS$_{PRO}$ are the same as the intended use, indications for use and performance of the predicate devices.
We did not use any new technology in this system, so those differences between our new system and its predicate do not affect the safety and effectiveness (SE).

0. General information of both devices is the same
1. Intended use and indications/principle of operations of both devices are the same.
2. There are minimum differences in the technological characteristic/performance data of the proposed device and those of the predicate devices, nevertheless, all of them comply with IEC 60601-1-2, IEC 60601-2-10. Thus the SE is not affected.

Based on the information provided in this premarket notification, Medical Cables, S.L. concludes that WIEMS$_{PRO}$ is substantially equivalent to the predicate devices with regard to safety and effectiveness.