August 25, 2022

Medical Cables S.L.
José Fuertes Peña
Manager
Calle Ferrocarril del Puerto 18 - Oficina 3-4
Málaga, Málaga 29002
Spain

Re: K211298
Trade/Device Name: WIEMSPRO
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 7, 2022
Received: July 21, 2022

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/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,

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211298

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 the 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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	WIEMSPRO

510(k) Summary

DATE OF SUBMISSION: 2021-03-18
DATE PREPARED: 2021-03-18

SUBMITTER NAME: Medical Cables, S.L.
SUBMITTER ADDRESS: Calle Ferrocarril del Puerto 18 - Oficina 3-4
29002, Malaga
SPAIN

CONTACT: José Fuertes Peña
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e-mail: jfuertes@medicalcables.eu

DEVICE TRADE NAME: WIEMSPRO
COMMON NAME: Powered muscle stimulator.
CLASSIFICATION NAME: Stimulator, Muscle, Powered, For Muscle Conditioning
(21 CFR 890.5850)

PREDICATE DEVICE(S): WIEMSPRO (K181955)

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.

WIEMSPRO 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.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:
In the establishment of substantial equivalence, the WIEMSPRO device is compared with the following previously cleared devices:

- WIEMSPRO (K181955)

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS			
Characteristic / Feature	CLEARED DEVICE WIEMSPRO	MODIFIED DEVICE WIEMSPRO	Comparison
GENERAL COMPARISON			
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	K181955	K211298	N/A
INTENDED USE			
Indications for use	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.	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 deviceis specifically designed as an addition toother 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.	Same
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	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	Same

	any kind. It is designed to be used together with a WIEMSPRO Mobile Application.	any kind. It is designed to be used together with a WIEMSPRO Mobile Application.	
TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE			
Powered Muscle Stimulator	YES	YES	Same
Power Source	Non-removable lithium polymer battery Battery: 3.7 V – 2,4AH (LiPo)	Non-removable lithium polymer battery Battery: 3.7 V – 2,4AH (LiPo)	Same
Method of line current isolation	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)	Same
Battery operated	YES	YES	Same
Number of output modes	One output mode, but with varying stimulation frequency and duty cycle ranges.	One output mode, but with varying stimulation frequency and duty cycle ranges.	Same
Regulated current or regulated voltage?	YES, regulated current	YES, regulated current	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, push on On/Off button directly pause the program	Yes, push on On/Off button directly pause the program	Same
Indicator display	Yes	Yes	Same
Device weight	300 g	300 g	Same
Dimensions (in.) [W x H x D]	[6,66 x 3,27 x 1,18] in	[6,66 x 3,27 x 1,18] in	Same
Waveform (e.g., pulsed monophasic, biphasic) (program per program)	Symmetrical biphasic (all programs)	Symmetrical biphasic (all programs)	Same
Number of programs	20	20	Same
Current / Voltage	125mA/62.5V	125mA/62.5V	Same

Plastic Housing Materials	PLASTIC	PLASTIC	Same
Maximum output voltage	170V	170V	Same
Maximum output current	125mA	125mA	Same
Maximum increment in output current	Limited to increments of 15% in steps of one mA	Limited to increments of 15% in steps of one mA	Same
Maximum power density	9,61mW/cm^2@500ohm	9,61mW/cm^2@500ohm	Same
Maximum current density	1,92mA/cm^2 Smallest electrode size: 65 cm ^{2}	1,92mA/cm^2 Smallest electrode size: 65 cm ^{2}	Same
Number of Output channels	1 CHANNEL	1 CHANNEL	Same
Independent channels with possibility to regulate the current individually	10 CHANNELS	10 CHANNELS	Same
Pulse duration (width)	100-400usec	100-400usec	Same
Frequency	1-100 HZ	1-100 HZ	Same
Reusable pads	YES	YES	Same
Software/Firmware/Microprocessor Control?	YES, Stimulator Software Ver 01	YES, Stimulator Software Ver 02	Similar
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 60601-1-6:2010 IEC 60601-2-10:2012 FCC 47 CFR Part 15 IEC 62304:2006 ISO 14971:2007 ANSI/AAMI ES60601-1: 2005 / A2:2010	Same

The difference presented above do not impact the equivalence of the subject device when compared to the predicate devices.

INTENDED USE:
Same as the predicate device.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:
Same as the predicate device.

SUMMARY DISCUSSION OF CLINICAL DATA:

510(k) Summary

Same as the predicate device. No clinical studies provided.

CONCLUSIONS:
We believe the intended use, the indications for use and principle of operation of WIEMSPRO are the same as the intended use, indications for use and performance of the predicate device.

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 no differences in the technological characteristic/performance data of the proposed device and those of the predicate device. Thus, the SE is not affected.

Based on the information provided in this premarket notification, Medical Cables, S.L. concludes that Cleared WIEMSPRO is substantially equivalent to the WIEMSPRO device with regard to safety and effectiveness.