May 26, 2022

I-Motion Group Global Iberica S.L.
Jose Soto Belloso
Managing Director
Calle Loeches 66.8 CP
Alcorcon, Madrid 28925
Spain

Re: K212413
Trade/Device Name: I-Motion, I-Motion Fit
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 25, 2022
Received: April 26, 2022

Dear Jose Soto Belloso:

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 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

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)*
K212413

Device Name
I-Motion
I-Motion Fit

Indications for Use *(Describe)*

I-MOTION intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The I-MOTION is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the I-MOTION training programs is designed for injured or ailing muscles and its use on such muscles is contra indicated.

I-MOTION 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.

I-MOTION electrical impulses allow the triggering o faction potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor end plate 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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1. INFORMATION

DATE OF SUBMISSION: 2021-April-01
SUBMITTER NAME: I-MOTION GROUP GLOBAL IBERICA S.L.
SUBMITTER ADDRESS: Calle Loeches 66.8
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SPAIN

CONTACT: Jose Luis Soto Belloso
TELEPHONE: +34 914 93 88 45

e-mail: jl.soto@i-motion.es

DEVICE TRADE NAME: I-Motion, I-M**otion Fit**
COMMON NAME: Powered muscle stimulator.
CLASSIFICATION NAME: Stimulator, Muscle, Powered, For Muscle Conditioning (21 CFR 890.5850)
PREDICATE DEVICE(S): WiEMSpro (K181955)

2. 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. None of I-MOTION training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

I-MOTION is a device for electronic muscle stimulation based on EMS technology. As for its use, the device is specifically designed as a complement to other sports and to train muscles. It must be used only for healthy muscles and clients, not for rehabilitation purposes. The device must be worn over the user's cotton underwear, therefore, the electrodes do not come into direct contact with the client. The I-MOTION System cannot be used while the user is moving or lifting weights.

3. SUMMARY OF COMPARISON WITH PREDICATE DEVICE

In the establishment of substantial equivalence, the I-Motion device is compared with the following previously cleared devices:

- WiEMSpro (K181955)

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS			
Characteristic / Feature	**PROPOSED DEVICE I-Motion**	**PREDICATE 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	N/A
INTENDED USE			
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 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 reatment of medical diseases or medical conditions of any kind..	Same
Indications for use	I-MOTION is intended to stimulate healthy muscles in order to improve or facilitate muscle performance, is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of I-MOTION training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. Each of the I-MOTION training programs 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. I-MOTION is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, I-MOTION is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles, not for	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	Similar. Difference is the Software application which controls the device, not affecting the safety, efficiency, or functionality of the device.

	rehabilitation purposes.	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.	
Prescription/ Rx	Prescription only	Prescription only	Same
Use environment	Use in athletic training facilities. Not for use outdoors	Use in athletic training facilities. Not for use outdoors	Same
Anatomical sites	Electrodes can be applied to multiple anatomical sites.	Electrodes can be applied to multiple anatomical sites.	Same
TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE			
Powered Muscle Stimulator	YES	YES	Same
Power Source	Battery:2 x 3.7 V= 7,4V – 3,4AH (Lithium)	Battery:3.7V–2,4AH (LiPo)	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.

510(k) SUMMARY

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, lithium polymer cell rechargeable	YES, lithium polymer cell rechargeable	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
Number of Output channels - Synchronous or Alternating? -Method of Channel Isolation	1 CHANNEL Alternating	1 CHANNEL Alternating	Same
Independent channels with possibility to regulate the current individually	10 CHANNELS	10 CHANNELS	Same
Current / Voltage	90mA/45V	125mA/62.5V	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.
Regulated current and/or voltage	Yes, regulated current	Yes, regulated current	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.

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
-On/Off status?	Yes	Yes	Same
-Low Battery?	Yes	Yes	Same
Voltage/Current level?	Yes	Yes	Same
Pulse duration (width)	150-450 µsec	100-400 µsec	Same
Frequency	1-100 Hz	1-100 Hz	Same
Time range (minutes)	Maximum program: unlimited	Maximum program: unlimited	Same
Plastic Housing Materials	PLASTIC	PLASTIC	Same
Device Weight	300 g	300 g	Same
Dimensions (in.) [W x H x D]	[5,3 x 2,7 x 1,7] in	[6,66 x 3,27 x 1,18] in	Similar

510(k) SUMMARY

Reusable Pads	Yes	Yes	Same
Compliance with voluntary standards / LAB tests performed	IEC 60601-1:2005 (ed. 3.0) + corrigendum 2006+ corrigendum 2007 + interpretation sheet 2008 + interpretation sheet 2009 + A1:2012 IEC 60601-1-6:2010 (ed.3.0) + A1:2013 IEC 60601-1-2-10:2010 (ed.2.0) + A1:2016 IEC 62304:2006 ISO 14971:2019	IEC 60601-1:2005 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	Similar All the corresponding standard norms are complied with, the minimum difference is due to the updating of the new versions of the norms.
Waveform (e.g., pulsed monophasic, biphasic) **(program per program)**	Symmetrical biphasic (all programs)	Symmetrical biphasic (all programs)	Same
Maximum output voltage	110V	170V	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.
Maximum output current	90mA	125mA	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device..
Maximum power density	9 mW/cm²@500ohm	9,61mW/cm²@500ohm	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.

Maximum current density	1,87mA/cm² Smallest electrode size: 48cm²	1,92mA/cm² Smallest electrode size:65cm²	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.
For interferential modes only: **Beat Frequency (Hz)**	N/A	N/A	N/A
For multiphasic waveforms only: **Symmetrical phases?**	N/A	N/A	N/A
Phase Duration (include units) **(state range, if applicable)** **(both phases, if asymmetrical)**	N/A	N/A	N/A
Net Charge (µC per pulse) **(If zero, state method of achieving zero net charge.)**	N/A	N/A	N/A
Maximum Phase Charge, (µC)	N/A	N/A	N/A
Burst Mode (i.e., pulse trains)	N/A	N/A	N/A
ON Time (seconds)	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A
Electrodes	Silicone conductive electrodes; reusable They never come into direct contact with the skin, as	Conductive fabric, reusable electrodes (not in direct contact with skin)	Same

	cotton covers and garments are used on the user's body. 9 pairs of electrodes, stimulating only one muscle group at a time Sizes: 96 cm2 and 48 cm2	9 electrode pairs and each pair of electrodes moves only one group of muscle simultaneously. Sizes: 65 cm_2 83 cm_2	
Connection electrodes with stimulator/cables	PIN 2 mm	Lead wires Stainless steel snap fastener	Similar Minimal differences in the technical characteristic/performance, not affecting the safety, efficiency, or functionality of the device.
Conductivity médium	The subject needs to put on an 100% hygroscopic cotton underwear (surgery textile, biocompatibility certified) and these underwear needs to be soaked/irrigated with normal tap water. So the electro conductive media is simply tap watered cotton which is in contact with the electrodes. The surface of the electrode will not get dry. In this case the pulse transmission efficiency will not decrease. The small conductive pads are washable and disinfectable.	The subject needs to put on an 100% hygroscopic cotton underwear (surgery textile, biocompatibility certified) and these underwear needs to be soaked/irrigated with normal tap water. So the electro conductive media is simply tap watered cotton which is in contact with the electrodes. The surface of the electrode will not get dry. In this case the pulse transmission efficiency will not decrease. The small conductive pads are washable and disinfectable.	Same

None of the differences presented above impact the equivalence of the subject device when compared to the predicate devices.

4. INDICATIONS FOR USE

As established in the Indications for Use Statement:

I-MOTION intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The I-MOTION is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.None of the I-MOTION training programsis designed for injured or ailing muscles and its use on such muscles is contraindicated.

I-MOTION 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.

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.

None of I-MOTION training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

5. SUMMARY DISCUSSION OF NON-CLINICAL DATA

The proposed device has been subject to be 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 tests conducted under foreseeable operating conditions showed proper operation of the device according to its intended use, including specifically:

- 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 I-MOTION device was tested to FCC requirements and found to comply with the requirements of 47CFR Part15 n15.107and n15.109.

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

- IEC 60601-1:2005 3rd edition
- IEC 60601-1-2:2007
- IEC 60601-2-10:2012

- IEC 60601-1-6 Edition 3.1 2013-10

6. SUMMARY DISCUSSION OF CLINICAL DATA

Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence.

7. CONCLUSIONS

We believe the intended use, the indications for use and principle of operation of I-MOTION 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).

1. General information of both devices is the same
2. Intended use and indications/principle of operations of both devices are the same.
3. There are minimum differences in the technological characteristic/performance at a of the proposed device and those of the predicate devices, nevertheless, all of them comply with IEC60601-1-2, IEC60601-2-10. Thus, the SE is not affected.

Based on the information provided in this pre-market notification, concludes that I-MOTION is substantially equivalent to the predicate device regarding safety and effectiveness.