June 6, 2023

Creative Fitness Developments S.L.
Jose Luis Delgado
Official Correspondent
Alfahuir 40,
Valencia 46020, Spain

Re: K230261
Trade/Device Name: Gnesis EMS Plus
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 30, 2022
Received: January 31, 2023

Dear Jose Luis Delgado:

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 -S

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.

Submission Number *(if known)*

K230261

Device Name

Gnesis EMS Plus

Indications for Use *(Describe)*

Gnesis EMS Plus 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 Gnesis EMS Plus training programs is designed for injured or ailing muscles and its use on such cases is contraindicated.
Each of Gnesis EMS Plus training programs, depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), is designed for a specific type of exercise.
Gnesis EMS Plus is a device for electronic muscle stimulation based on EMS technology.
Gnesis EMS Plus is specifically designed as an addition to other sports and for training muscles. It must be used only on healthy muscles, not for rehabilitation purposes.

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.

510(k) Summary

Creative Fitness Developments S.L.

Gnesis EMS Plus

K230261

1. SUBMITTER

Manufacturer Name**:**	Creative Fitness Developments S.L. Av. Alfahuir 40 46020 Valencia (Spain) +34.628.09.96.67
Official Contact:	José Miguel Requena García Av. Alfahuir 40 46020 Valencia (Spain) +34.628.09.96.67 support@gnesisofficial.com
510(k) Summary Preparation Date:	01 June 2023
510(k) Number:	K230261

2. DEVICE

Trade/Proprietary Name:	Gnesis EMS Plus
Common name:	Powered muscle stimulator
Regulation Number:	21 CFR 890.5850
Regulation Name:	Powered muscle stimulator
Regulatory Class:	Class II
Product Code:	NGX

3. PREDICATE DEVICE

Name & 510(k) Number:	WIEMSpro, K181955
	I-MOTION, K212413
Manufacturer Name:	Medical Cables S.L.
	I-Motion Group Global Iberica S.L

4. DEVICE DESCRIPTION

Gnesis EMS Plus is an electro-medical device intended for stimulating healthy muscles in order to improve or facilitate muscle performance. It is designed for personal training.

None of Gnesis EMS Plus training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. It must be used only on healthy muscles and patients, it is not designed for rehabilitation purposes.

The device must be worn over the underwear provided by the system manufacturer, ensuring that the electrodes do not come into direct contact with the patient's skin.

Gnesis EMS Plus System cannot be used while the user is performing demanding tasks, such as jumping or lifting weights, any exercise must be approved by a qualified trainer.

Genesis EMS Plus System includes the stimulator device, EMS suit with integrated electrodes, electrode wiring, specific underwear, stimulator charger (Off-the-shelf USB-C PD 3.0) and control device (Off-the-shelf Android Tablet with custom application)

5. INDICATION FOR USE

Gnesis EMS Plus 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 Gnesis EMS Plus training programs is designed for injured or ailing muscles and its use on such cases is contraindicated.

Each of Gnesis EMS Plus training programs, depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), is designed for a specific type of exercise.

Gnesis EMS Plus is a device for electronic muscle stimulation based on EMS technology.

Gnesis EMS Plus is specifically designed as an addition to other sports and for training muscles. It must be used only on healthy muscles, not for rehabilitation purposes.

6. SUMMARY OF COMPARISON WITH PREDICATE DEVICE

In the establishment of substantial equivalence, the Gnesis EMS Plus device is compared with the following previously cleared devices:

- WiEMSpro (K181955)
- I-Motion (K212413)

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	**Proposed device**	**Predicate device 1**	**Predicate device 2**	**Comparison**
	Gnesis EMS Plus	**WIEMSPRO**	**I-Motion**	
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	K230261	K181955	K212413	
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 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.	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.	Same
Indication for use	Gnesis EMS Plus 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 Gnesis EMS Plus training programs is designed for injured or ailing muscles and its 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	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	Similar. All three devices are designed for improving healthy muscle training.

	on such cases is contraindicated. Each of Gnesis EMS Plus training programs, depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), is designed for a specific type of exercise. Gnesis EMS Plus is a device for electronic muscle stimulation based on EMS technology. Gnesis EMS Plus is specifically designed as an addition to other sports and for training muscles. It must be used only on healthy muscles, not for rehabilitation purposes.	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 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.	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. I-MOTION 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 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.	
Prescription / Rx	Prescription only	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.	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.	Electrodes can be applied to multiple anatomical sites.	Same
TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE				
Powered Muscle Stimulator	YES	YES	YES	Same
Power source	Battery:3 x 3.6 V= 10,8V - 3,20AH (Lithium)	Battery:3.7V-2,4AH (Li Po)	Battery:2 x 3.7 V= 7,4V - 3,4AH (Lithium)	Similar Higher input voltage to improve efficiency and battery life. Doesn't affect safety, performance/ functionality of the device.
Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)	Same
Patient leakage Same current -Normal condition -Single fault condition	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	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	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	1 CHANNEL Alternating	Same
Independent channels with possibility to regulate the current	12 CHANNELS	10 CHANNELS	10 CHANNELS	Two extra channels, all channels are identical and conforming to

individually				regulations
Regulated current and / or voltage	Regulated current	Regulated current	Regulated current	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Same
Automatic overload Trip?	Yes	Yes	Yes	Same
Automatic No-load trip?	Yes	Yes	Yes	Same
Automatic Shut Off?	On/Off switch Power-save timer	On/Off switch	On/Off switch	Adds power save timer, active only when device is not connected to control App and not delivering treatment.
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
Indicator Display?	Yes	Yes	Yes	Same
Plastic Housing materials	No, aluminum	Plastic	Plastic	Different material, safety tested according to IEC 60601-2-10 for leakage currents
Device weight	500 g	300 g	300 g	Heavier because of aluminum construction
Dimensions	[5,5 X 4 X 1,2] in	[6,66 x 3,27 x 1,18] in	[5,3 X 2,7 X 1,7] in	Similar
Waveform (e.g., pulsed mono-phasic, bi-phasic) (program per program)	Symmetrical bi-phasic (all programs	Symmetrical bi-phasic (all programs	Symmetrical bi-phasic (all programs	Same
Number of programs	10 plus customizable	20	--	Different approach to program

				definition
Current/ Voltage	120mA/85V	125mA/170V	90mA/110V	Higher current than i-motion, similar to WIEMSPRO
Maximum power density	14,4mW/cm2@500ohm	9,61mW/cm2@500ohm	9mW/cm2@500ohm	Higher power density, included in risk management file according to IEC 60601-2-10 clause 201.4.2 This is due to higher frequencies available, resulting in higher duty cycle, not used in practice.
Maximum current density	2 mA/cm2 Smallest electrode size: 60 cm2	1,92mA/cm2 Smallest electrode size: 65 cm2	1,87mA/cm2 Smallest electrode size: 48cm2	Similar
Pulse duration (width)	25-400 µs	150-450 µs	150-450 µs	Allows for lower pulse durations, doesn't introduce any risk as in this case energy density is lower, complies with IEC 60601-2-10 accuracy limits
Frequency	1 -150 Hz	1 -100 Hz	1 -100 Hz	Allows for higher frequencies, complies with IEC 60601-2-10 limits
Time range (minutes)	Maximum program: 90 minutes	Maximum program: unlimited	Maximum program: unlimited	More restrictive
Reusable pads	Yes	Yes	Yes	Same
Compliance with voluntary standards / LAB tests performed	IEC 60601-1:2005 + COR1:2006 + COR2:2007 + AMD1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010 IEC 60601-2-10:2012	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	IEC 60601-1:2005 (ed. 3.0) +corrigendum 2006+ corrigendum 2007 + interpretation sheet 2008 +interpretation sheet 2009 +A1:2012	Similar

	IEC 62304:2006 ISO 14971:2007	ANSI/AAMI ES60601-1: 2005 / A2:2010	IEC 60601-1-6:2010 (ed.3.0) + A1:2013 IEC 60601-1-2:2014 IEC 60601-2-10:2012 + A1:2016 IEC 62304:2006 ISO 14971:2019	

7. NON-CLINICAL TESTING

During the development of the Gnesis EMS Plus System the following non-clinical tests have been performed to validate the adequate performance of the system and equivalence to other systems in the market.

- Internal laboratory tests for waveform quality, responsiveness of controls, parameter regulation accuracy, battery life and reliability.
- EMC testing according to the procedures defined in IEC 60601-1-2 by external certification authority.
- Safety testing according to IEC 60601-1 and IEC 60601-2-10 by external certification authority.

8. CLINICAL TESTING

Gnesis EMS Plus System implements Electrical Muscle Stimulation technology, which is a very well known and proved technology.

The system implements no significant differences form the clinical point of view, therefore no additional clinical testing was necessary to prove the performance of the device, apart from performance and safety testing.

9. CONCLUSIONS OF COMPARISON WITH PREDICATE DEVICES

The predicate devices: I-Motion and WIEMSPRO are currently marketed in US and approved by FDA with their respective 510(k) numbers.

Indications for use of Gnesis EMS Plus and WIEMSPRO are almost identical to those of I-Motion, as I-Motion is the main comparison device in both cases.

The above table shows Gnesis EMS Plus has equivalent technical characteristics, while observing the following minor differences:

- Gnesis EMS Plus uses a higher voltage battery, this affects power efficiency and battery life but has no effects on the treatment or battery safety. Cells comply with IEC 62133-2:2007 "Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems"
- Gnesis EMS Plus has 12 channels. Wiempspro and I-Motion have 10. This allows for the treatment of more muscle groups, all channels have the same technical characteristics and comply with IEC 60601-2-10
- Gnesis EMS Plus has on/off switch and Power-saver timer. Wiemspro and I-Motion have only on/off switch. Power-saver timer only works in case the device is disconnected from control application and treatment is not active.
- Gnesis EMS Plus is made of aluminum, Wiempspro and I-Motion of plastic. Safety tested according to IEC 60601-2-10 for leakage currents and impact resistance.
- Gnesis EMS plus weights 500 gr.; Wiemspro and I-Motion weigh 300 gr.
- Gnesis EMS Plus has 10 programs customizable; Wiemspro has 10, I-Motion has none. All parameters are limited to the ranges mandated in IEC 60601-2-10
- Gnesis EMS Plus provides higher power and current densities and provides a wider range of adjustment of waveforms. All parameters are inside specified limits in IEC 60601-2-10

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 all three devices comply to the same main standards, Gnesis EMS Plus can be considered substantially equivalent to the predicate devices I-Motion and WIEMSPRO.

10. CONSENSUS STANDARDS

In order to ensure adequate performance and safety of the Gnesis EMS Plus system, it has been tested by an accredited laboratory (SGS Tecnos Spain) according to the following standards:

- Electromagnetic compatibility:
    - **UNE-EN 60601-1-2:2015**, Spanish adopted version, identical to **IEC 60601-1-2:2014** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
    - **UNE-EN 60601-2-10:2015+A1:2016**, Spanish adopted version, identical to **IEC 60601-2-10:2012+AMD1:2016** Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- Safety:
    - **UNE-EN 60601-1:2008 + Err.:2008 + Corr.:2010 + A1:2013 + A12:2015**, Spanish adopted version, identical to **IEC 60601-1:2005 + COR1:2006 + COR2:2007 + AMD1:2012** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    - **UNE-EN 60601-1-6:2010 + A1:2015**, Spanish adopted version, identical to **IEC 60601-1-6:2010+AMD1:2013** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    - **UNE-EN 60601-2-10:2015+A1:2016**, Spanish adopted version, identical to **IEC 60601-2-10:2012+AMD1:2016** Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
    - **IEC 62304:2006+AMD1:2015 CSV** Medical device software - Software life cycle processes
    - **ISO 14971:2019** Medical devices - Application of risk management to medical devices

Equivalence of UNE-EN and IEC standards can be checked in: https://www.en.une.org/