May 14, 2019

Casgarum Investment, S.L.
Rafael Castillo
General Manager
Calle Real, 17 Bº E
45200, Illescas
Toledo, Spain

Re: K181419
Trade/Device Name: FLIX-EMS
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 12, 2018
Received: October 1, 2018

Dear Rafael Castillo:

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 Pinto, PhD
Assistant Director, Acute Injury Team
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181419

Device Name
FLIX-EMS

Indications for Use *(Describe)*
FLIX-EMS device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

FLIX-EMS is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the FLIX-EMS 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 FLIX-EMS programs is definitely not suitable for rehabilitation and physiotherapy.

FLIX-EMS 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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DATE OF SUBMISSION: 2018-04-19

SUBMITTER NAME: CASGARUM INVESTMENT, S.L.
SUBMITTER ADDRESS: Calle Real, 17 Bº E
45200, Illescas
Toledo, Spain

CONTACT: Rafael Castillo
TELEPHONE: +34 925 51 26 67

e-mmail: rcasgarum@gmail.com

DEVICE TRADE NAME: FLIX-EMS
COMMON NAME: STIMULATOR, MUSCLE, POWERED
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 proposed device is an electro-medical device designed and manufactured for sports and fitness activity with low-intensity electro-stimulation technology. It is intended for stimulating healthy muscles in order to improve or facilitate muscle performance in training procedures with numerous special features.

When used as indicated, FLIX-EMS device is intended for muscle electro-stimulation. Low-intensity electro-stimulation simulates how our central nervous system activates muscle movement. Muscles move thanks to nerve impulses from the brain. These electrical stimuli are passed along nerves to the muscles, where they generate muscle contractions. Low-intensity electro-stimulation uses the same system to encourage muscle training.

The various muscle groups are stimulated using electrodes strategically positioned around the body to generate muscle contractions. The training dynamic combines voluntary movements by the user with muscle contractions generated by the low-intensity electro-stimulation, meaning that the muscle receives more effective stimulation and, in short, a more complete workout.

The electrodes cover most muscle groups and these are activated simultaneously so that the user can train various muscle groups at the same time. The user can train biceps and triceps at the same time, for example, which cannot be done with conventional weight training.

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The device consists of an app (dashboard) that enables operating variables to be selected and monitored, an electronic device that controls the selected power supply and a Bluetooth data transmission system.

The suit contains a set of cables that carry the current via an emission system (electrodes) and is connected to the main unit via a master cable.

The FLIX-EMS app enables very simple and convenient operation of all the system software (program). The app is used by physically touching the screen on the terminal in which the app is installed, whether a smartphone, tablet or PC:

The software is a computer program that uses images and graphics to represent the available information and options. Its main purpose is to provide a simple visual interface for enabling communication with the device's operating system.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

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

- E-Fit EF-1280 (K133225)
- Compex Wireless USA (K170903)

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	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				
Intended use	FLIX-EMS device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. FLIX-EMS is not	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	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.	Same FLIX-EMS does not include TENS

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
	intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the FLIX-EMS 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 FLIX-EMS programs is definitely not suitable for rehabilitation and physiotherapy. FLIX-EMS 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	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 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	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. The Compex Wireless USA TENS is used for: • temporary relief of pain	

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
		Session duration), different types of muscle work can be imposed 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.	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.	
Indications for use	To be used by adults only. Must be used for only healthy muscles and clients. 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 the Flix-ems application for tablets.	To be used by adults only. 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.	To be used by adults only. 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)
Prescription/OTC	Prescription use	Prescription use	Over-the-counter	Same as E-fit. Different than Compex
Use environment	Use in athletic training facilities. Not for use outdoors	Use in athletic training facilities	Use in athletic training facilities. Outdoor use not restricted	Similar as E-fit and Compex. FLIX-EMS only for indoor use
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	8.4V(3400mA). Two cells Lithium-ion	12V – 3,4AH	Remote: Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 1500[mAh Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 450[mAh]	Similar FLIX-EMS, is fully portable, the battery needs to be Li-ion battery, which is similar to Compex battery

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
Battery operated	YES	YES	YES	Same
Regulated current and/or voltage	YES, current	YES, current	YES, current	Same as Efit Same as Compex Wireless USA
Current / Voltage	70mA/100V	72mA/36V	100mA/135V	Similar to Efit Similar to Compex Wireless USA
Plastic Housing Materials	PLASTIC	STAINLESS STEEL	PLASTIC	Different than Efit Similar to Compex
Maximum Output Voltage (V) (+/- 10%)	Toning 1: 35V @500Ω 100V@2kΩ 100V@10kΩ Toning 2: 35V 100V@2kΩ 100V@10kΩ Training 1: 35V @500Ω 100V@2kΩ 100V@10kΩ Training 2: 35V 100V@2kΩ 100V@10kΩ Training 3: 35V @500Ω 100V@2kΩ 100V@10kΩ Training 4: 35V 100V@2kΩ 100V@10kΩ Customisable programs: 35V @500Ω 100V@2kΩ 100V@10kΩ	36 V @ 500 Ω	Endurance: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Resistance: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Strength: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Explosive Strength: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Potentiation: 60 V @ 500 Ω 152 V @ 2 kΩ 132 V @ 10 kΩ Training Recovery: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Competition Recovery: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Pre Warmup	Similar to Efit (@500 Ω: Toning 1, Toning 2, Training 1, Training 2, Training 3 and Training 4) Similar to Compex Wireless USA (Maximum output voltage is higher for Compex Wireless in all training programs) Flix-EMS has limited output voltage to 100 V

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
			60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Muscle Relaxation: 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ Pain Relief TENS: 180 [V] peak on 10[kΩ] 170 [V] peak on 2 [kΩ] 58 [V] peak on 500 [kΩ]	
Maximum Output Current (mA) (+/- 10%)	Toninig 1: 70 mA @500Ω 50 mA @ 2kΩ 10 mA @ 10kΩ Toning 2: 70 mA @500Ω 50 mA @ 2kΩ 10 mA @ 10kΩ Training 1: 70 mA @500Ω 50 mA @ 2kΩ 10 mA @ 10kΩ Training 2: 70 mA @500Ω 50 mA @ 2kΩ 10 mA @ 10kΩ Training 3: 70 mA @500Ω 50 mA @ 2kΩ 10 mA @ 10kΩ Training 4: 70 mA @500Ω 50 mA @ 2kΩ 10 mA @ 10kΩ Customisable programs: 70 mA @500Ω 50 mA @ 2kΩ	72 mA @ 500 Ω	Endurance: 116 mA @ 500 Ω 80 mA @ 2 kΩ 15 mA @ 10 kΩ Resistance: 116 mA @ 500 Ω 80 mA @ 2 kΩ 17 mA @ 10 kΩ Strength: 113 mA @ 500 Ω 80 mA @ 2 kΩ 15 mA @ 10 kΩ Explosive Strength: 81 mA @ 500 Ω 81 mA @ 2 kΩ 15 mA @ 10 kΩ Potentiation: 117 mA @ 500 Ω 80 mA @ 2 kΩ 16 mA @ 10 kΩ Training Recovery: 116 mA @ 500 Ω 81mA @ 2 kΩ 16 mA @ 10 kΩ Pre Warmup 116 mA @ 500 Ω 81 mA @ 2 kΩ 15 mA @ 10 kΩ	Similar to Efit (@500 Ω: Toning 1, Toning 2, Training 1, Training 2, Training 3 and Training 4) Similar to Compex Wireless USA (Maximum output current is higher for Compex Wireless in all training programs)

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
	10 mA @ 10kΩ		Muscle Relaxation: 116 mA @ 500 Ω 81 mA @ 2 kΩ 16 mA @ 10 kΩ Pain Relief TENS: 18[mA] peak @10[kΩ] 86[mA] peak@2[kΩ] 116[mA] peak@500[Ω]	
Maximum power density	4.08 mW/cm^2@500Ω (Smallest electrode)	6.3 mW/cm^2 @500Ω	27.6 mW/cm^2 @ 500Ω	Similar to Efit Different than Compex Wireless USA (Compex USA features a much higher value)
Maximum current density	1.45 mA/cm^2 @ 500Ω (Smallest electrode)	0.85 mA/cm^2 @ 500Ω	4.8 mA/cm^2 @ 500Ω	Similar to Efit Different than Compex Wireless USA (Compex USA features a much higher value)
Number of Output channels -Synchronous or Alternating? -Method of Channel Isolation	1 CHANNEL 1 output channel can shift in time to the 10 outputs but electrical current can be regulated individually on every outputs.	1 CHANNEL 1 output channel can shift in time to the 12 outputs but electrical current can be regulated individually on every outputs	4 CHANNELS Synchronous with 2msec delay between channels	Similar than E-fit Different than Compex Wireless USA
Waveform (e.g., pulsed monophasic, biphasic) (program per program)	Symmetric 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):	Same as Efit (All programs 'symmetric biphasic' in both cases) Similar to Compex Wireless USA (all programs 'symmetric biphasic' expect for the 'Pain relief – TENS' but no TENS included in the FLIX-EMS

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
			Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Muscle Relaxation (same as Massage): Symmetrical Biphasic -Pain relief TENS (same as FM): Balanced, asymetrical Biphasic	Device)
Pulse width (μs)	50-400(μs) Toning 1: 350 (μs) Toning 2: 350 (μs) Training 1: 350 (μs) Training 2: 150 (μs) Training 3: 350 (μs) Training 4: 400 (μs) Customisable programs: 50-400(μs)	100-500(μs)	Endurance: 200-400 (μs) Resistance: 200-400 (μs) Strength: 200-400 (μs) Explosive strength: 200-400 (μs) Potentiation 200-400 (μs) Training recovery: 200-400 (μs) Competition recovery: 200-400 (μs) Pre warmup: 200-400 (μs) Muscle relaxation: 200-400 (μs) Pain Relief TENS: 70 to 300[μs] (measured at 50% of positive pulse)	Similar to Efit (all programs within the range of pulse of Efit except for the 'customisable') Similar to Compex Wireless USA (all programs within the range of Compex except for the 'customisable')
Frequency	5-100 HZ Toning 1: 85 Hz Toning 2: 90 Hz	5-120 HZ	0,5 to 122 Hz Endurance: 10 Hz Resistance: 50 Hz	Similar to Efit (all programs of FLIX-EMS within the frequency range of the Efit)

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
	Training 1: 7 Hz Training 2: 100 Hz Training 3: 50 Hz Training 4: 50 Hz Customisable program: 5-100 HZ		Strength: 75 Hz Explosive strength: 100 Hz Potentiation: From 1 to 75 Hz Training recovery: 10 Hz Competition recovery: 0,5 Hz Pre warmup: 4 Hz Muscle relaxation: 1 Hz Pain Relief TENS: 5 to 122 Hz	Similar to Compex Wireless USA (all programs of FLIX-EMS within the range of the Compex)
Reusable pads	YES	YES	NO	Same as Efit Different than Compex
Number of programs	6 pre-set programs + 3 customizable programs	5+5	22 programs	Similar to Efit Different than Compex Wireless USA
Program duration	25 min	Maximum 30min	Maximum 60 minutes	Similar to Efit Different than Compex
Electrode dimensions (cm)	12x8x0.1 cm 8x6x0.1 cm	Electrodes with pre-defined (supplied with the device) size and correct position	10x5 cm and 5x5 cm self-adhesive pads (FDA cleared)	Similar to Compex Wireless USA
User interface	Application on tablet or mobile with Android and Bluetooth communication. If the communication fails, the device has a protection so as not to damage the user. Through the program the level of each channel assigned to each muscle is	The rotary encoder allows for a quick set-up and because of the push button capability, the program can be stopped immediately for every channel. There are large START/STOP and POWER off buttons to begin the program and for complete power	User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) Stimulation programs.	Similar, the FLIX-EMS is controlled by a tablet by Bluetooth but similar usability interface.

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
	regulated with its specific name and the parameters of each program are selected with their exact name and a START / STOP button that starts or stops the process.	shutdown. Because of the pictographs and fixed electrodes in the clothing, it is very easy to set the appropriate muscle groups.		
Portability / Mobile Use	Full portable and protected with silicone sleeve	Portable with difficulty, it is not an easy movable device.	Portable (small size)	Similar to Compex Different than E-fit
Operator	Only specialized trainers and certified in the sporting use of EMS	By manufacture recommendations, the only person who can operate the device must obtain certifications provided by the seller. This person must complete the certification prior to use on a patient.	Adults / trainers using EMS for training	Similar to Efit Similar to Compex
Menu / Settings	Only one level of menus, with previous selection of code coach and client code	Simple one-level menu system.	levels/sub-menus, complex menusystem	Similar to Efit Similar to Compex
Plugs	Cables connect to the electrodes with Ø1'8 mm miniature banana. Cables connect to the stimulator device with plastic 14 pin and 8 pin connectors.	Cables connect to the electrodes with snap fastener and connect to the machine with plastic 12pin waterproof ip68 connector.	Electrodes sticks to the skin and the modules slide along the electrode snap until it 'clicks'. They are not connected to the machine.	Different than Efit (cables connecting to the electrodes) Different than Compex
Conductivity of the electrodes	The subjects needs to wear a cotton bodywear and these bodywear 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 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 gel for electrotherapy is used in conjuction with the disposable elecrodes for conductivity	Similar to Efit Different than Compex

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COMPARISON OF TECHNOLOGICAL CHARACTERISTICS				
Characteristic / Feature	PROPOSED DEVICE FLIX-EMS	PREDICATE DEVICE E-Fit EF-1280	PREDICATE DEVICE Compex Wireless USA	Comparison
		conductive pads are washable and disinfectable.		
Placement of the electrodes	Appropriately pre-placed in specific areas according to muscle anatomy.	Appropriately pre-placed in specific areas according to muscle anatomy.	Self-adhesive on any area of the body.	Similar to Efit Different than Compex
Display	Display is on an android tablet (LCD touchscreen) with Bluetooth communication.	LCD 2x40 character LCD display with LED backlight.	Small -sized LCD color screen	Similar to Efit Similar to Compex
Statistical functions	It records in the tablet and then on the cloud server the total hours grouped by each client code and trainer.	Statistical functions – counting the hours of operation	Not available	Similar to E-fit
LAB tests performed	ANSI AAMI 60601-1 IEC 60601-1-2:2007 IEC 60601-1-6:2010 IEC 60601-2-10:2012 FCC 47 CFR Part 15 IEC 62304:2006	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 60601-1-11:2010 IEC 60601-2-10:2012	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 60601-1-6:2013 IEC 60601-1-11:2010 IEC 60601-2-10:2012 IEC 62304:2006	Similar to Efit Similar to Compex Wireless USA

INTENDED USE:

As established in the Indications for Use Statement:

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FLIX-EMS device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

FLIX-EMS is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the FLIX-EMS 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 FLIX-EMS programs is definitely not suitable for rehabilitation and physiotherapy.

FLIX-EMS 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 FLIX-EMS 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 recognized standards:

- ANSI AAMI 60601-1:2005/(R)2012 And A1:2012
- IEC 60601-1-2:2007

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- 60601-2-10 Edition 2.1 2016-04
- IEC 60601-1-6 Edition 3.1 2013-10
- ISO 14971 Second Edition 2007-03-01
- EN ISO 13485:2003 +/AC2009
- IEC 62304:2006

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 FLIX-EMS 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).

1. General information of the proposed and predicate devices is the same
2. Intended use and indications/principle of operations of proposed device and predicate devices are the same.
3. 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 and applicable collateral and particular standards. Thus, the SE is not affected.

Based on the information provided in this premarket notification, CASGARUM INVESTMENT, S.L., concludes that FLIX-EMS is substantially equivalent to the predicate device with regard to safety and effectiveness.