Fit-Pro Ltd.
Janos Papp
CEO
7 Szabadsag Ter
Budapest, 1054
Hungary

Re: K202148
Trade/Device Name: E-Fit Infinity System (EF-2090 Controller and EF-100 Unit)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 23, 2021
Received: July 23, 2021

Dear Janos Papp:

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

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)*
K202148

Device Name
E-Fit Infinity System (EF-100 +EF-2090)

Indications for Use *(Describe)*
The E-Fit Infinity System is designated to prescription use (Rx) only.

E-Fit Infinity system (EF-2090 and EF-100) is a machine system with electronic muscle stimulation based on EMS technology. Regarding its use, the output power is limited and specifically designed as an addition to other sports and for toning muscles. It may only be used for healthy muscles and clients, and not to be used for rehabilitation purposes.

The E-Fit Infinity system was designed to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit Infinity system must not be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the E-Fit Infinity system training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

The E-Fit Infinity system's 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 various types of muscle work that the E-Fit Infinity system can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit Infinity system may therefore be considered a technique of muscle training.

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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[redacted]

K202148 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

The assigned 510(k) number is: **K202148**

1. Submitter information (21 CFR 807.92(a)(1)):

Submitter:	**Fit-Pro Ltd.**
Address:	**6th floor, 7 Szabadsag square**
	Hungary, Budapest 1054
Phone number:	**0036304772460**
Contact person:	**Janos dr. Papp** **Managing Director**
Summary date:	**08 May 2020**

2. Device information (21 CFR 807.92(a)(2)):

Name of the device:	E-Fit Infinity System
Common name of the device:	Stimulator, Muscle, Powered, For Muscle Conditioning
Trade name of the device:	E-Fit EF-2090 and EF-100 Unit
Common name of the device:	E-Fit Infinity System
Classification:	21 CFR 890.5850, Class II, IPF

3. Identification of Legally Marketed Device(s) (21 CFR 807.92(a)(3)):

Name of the legally marketed device:	E-FIT EF-1280 EMS MACHINE
Manufacturer:	Fit-Pro Ltd.
510(k) number:	K133225

4. Description of the device (21 CFR 807.92(a)(4)):

E-Fit Infinity System (EF-2090 and EF-100) is a machine system with electronic muscle stimulation based on EMS technology. Regarding its use, the output power is limited and specifically designed as an addition to other sports and for toning muscles. It may only be used for healthy muscles and clients, and not to be used for rehabilitation purposes.

The E-Fit Infinity system was designed to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit Infinity system must not be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the E-Fit Infinity system training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

The E-Fit Infinity system's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons 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 various types of muscle work that the E-Fit Infinity system can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit Infinity system may therefore be considered a technique of muscle training.

4.1. Explanation of the E-Fit Infinity System functions

The E-Fit Infinity System with electrical muscle stimulation is the part of the E-FIT EMS model's family, which is also based on EMS technology. The device is specifically designed as an addition to other sports and for toning muscles. It may only be used for healthy muscles and clients, and not to be used for rehabilitation purposes

4.2. Scientific concepts that form the basis for the E-Fit Infinity System

The E-Fit Infinity System's electrical impulses allow to trigger action potentials on motor neurons (excitations). These excitations are transmitted to the muscle fibres 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, length of the session), different types of muscle work can be imposed on the stimulated area. The various types of muscle work that the E- Fit Infinity System can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit Infinity System may therefore be considered a technique of muscle training.

FIRMWARE SAFETY FEATURES:

4.2.1. Self-test

Safety feature to self-check all 12 channel's safe and proper functioning after turning the device on. If a channel's output signal falls out of the safe range, the device further use will be disabled, and the display will show 'SELFTEST FAILED'. The cause might be external factor (humidity, temperature) or any hardware malfunction.

4.2.2. Health protection

Health protection is a safety hardware-based feature to turn off the modulation and stop output signals if power amplifier panel transistors have shortcuts or multiple parallel outputs become active due to hardware or software error. Health protection always protects user from unpleasant electric sensation, even if main processor crashes.

4.2.3. Impulse-shift technology (IST)

IST, developed by E-Fit engineers, is a unique method that shifts impulses in time between different channels. This means that only one muscle group is stimulated at any given moment. Therefore, the full output performance of the device will be equal to the power of only one channel, reducing overall impulse-load on client. The biggest advantage of this solution is that cross-impulses between channel-pairs can be eliminated.

4.2.4. Electrical Conductivity test (no load trip)

No Load Trip test is an electrical conductivity test running continuously on every channel. It checks the electrical resistance of cables and electrodes in the specified range (~400Ω - ~20kΩ) on all channels. If a cable is broken or an electrode is not in proper contact, the given channel will turn off and will be marked red on the RUN screen. In this case conductivity (dampening) of electrodes and cable integrity must be checked. This test impulse package runs through fast at the end of each stimulation (signal parameters: bipolar, square impulses, P. Width: 100 µs, Freq.: 1 Hz, current power: 2 mA, length (12 bipolar channels): 0.02 sec).

4.3. Significant physical and performance characteristics of the E-Fit Infinity System

EF-100 wireless unit (ME device) technical parameters:

Unit size (calc.):	6.1 x 3.9 x 1.1" (155x98x28mm)
Unit weight (calc.):	0.88 lb (0.4kg)
Display:	Size: 3.2 inch
	type: RGB 65K true to life colors, TFT
	Resolution: 240 by 320 pixel

Memory:	Built in 4MB flash memory
Storage capacity:	2GB micro SD card
Battery:	Built in Li-Polymer 2x3.7V/3.2Ah
Runtime:	Up to 5 training hours
Ports:	2* 12 pin SP (jacket and short)
	1* 9 – 12V/1A DC
Supply connection:	1*12V DC
Wireless communication:	IEEE 802.15.4. RF module (FCC (USA), IC (Canada), ETSI (Europe) Certified)
Output:	Maximal power: 1.62W
	Maximal current density:
	0.9mA/cm2 Current intensity
	(peak): 0-75mA RMS
	current/channel: 2.975mA
	Voltage range: 0-48V
	No. of channels: 12
	Output waveform: Modulated bipolar square
	Impulse parameters:
	i. Frequency: 4-90Hz
	ii. Pulse width: 100-500µs
	iii. Contraction time: 0.1-30s
	iv. Relax time: 0.3-30s
	v. Ramp up time: 0-5s
	vi. Ramp Down time: 0-5s
	vii. Training time: 1-30min

User interface:	5*Pushbutton
	4* LED status feedback
	Graphic User Interface
	(GUI)

EF-2090 controller technical parameters:

Device size (calc.):	15 x 11.3 x 2.7” (380x286x69mm)
Device weight (calc.):	4.9 lb (2.2kg)
Display:	Size: 10.1 inch
	Type: Capacitive touchscreen, TFT
	View angle: 170°
	Maximal brightness: 350cd/m^2
	Resolution: 1280 by 800 pixel
Storage capacity:	32 GB SSD
Battery:	Built in Li-Ion 7.2V/2.6Ah
Runtime:	Up to 2 hours
Supply connection:	1*12V DC
Power consumption:	max. 60W
Wireless communication:	802.11 b/g/n (Range up to 50m)
	IEEE 802.15.4. RF module (FCC (USA), IC (Canada), ETSI (Europe) Certified)
User interface:	6* heavy duty encoders with push function
	1*multifunctional “E-button”
	Graphic touch screen User Interface (GUI)

5. Intended use of the device (21 CFR 807.92(a)(5)):

E-Fit Infinity System (EF-2090 and EF-100) is a machine system with electronic muscle stimulation based on EMS technology. Regarding its use, the output power is limited and specifically designed as an addition to other sports and for toning muscles. It may only be used for healthy muscles and clients, and not to be used for rehabilitation purposes.

The E-Fit Infinity system was designed to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit Infinity system must not be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the E-Fit Infinity system training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

The E-Fit Infinity system's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons 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 various types of muscle work that the E-Fit Infinity system can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit Infinity system may therefore be considered a technique of muscle training.

The device has one-channel amplifier that controls the 12 channels in time shifted way according to the previously adjusted parameters.

Therefore, unwanted cross-impulses are prevented between the electrodes. This technology ensures that during the operation it is not necessary to switch and/or replace the electrodes on the different body parts. This provides a long life for the electrodes and reduces any possibility of skin irritation. The electrodes are well-placed according to the direct placement standards: into designed cotton, portable uniform with an adjustable rubber band cover. Therefore, misplacement or any harmful risk-taking is physically impossible. (Ex. Neck area, head, genitals etc.)

User-friendly GUI helps the Operator to manage the System. Default programs (built-in by the manufacturer) are included in the Remote Controller. The parameters and the channel intensities can be adjusted separately according to the regulations and the given measuring protocol.

The main cable from the low-powered, and low-voltage output unit needs to be attached to the client's Technical Wear with the corresponding connectors, reversed or mismatched connections are not possible. The Technical Wear ensures that the electrodes will stay in place despite any misconnection of given electrodes due to operator error. The clients must wear underclothes designed by the manufacturer for hygiene and to save the condition of the electrodes. Placement of the electrodes is not allowed directly on the skin! The

electrodes are already fitted in the Technical Wear, the operator needs only to slightly reposition, according to the client's muscles. The electrodes can be conductive via tap water which is applied on the surface of the cotton layer during the treatment. The electrodes are washable and disinfectable.

The E-Fit Infinity System has the same intended use and similar technological characteristics and principles as the predicate device. Moreover, verification and validation tests contained in this submission demonstrate that the small differences in E-Fit Infinity System still maintains the same safety and effectiveness as that of the cleared device. In other words, those engineering differences do not affect the intended use or alter the fundamental scientific technology of the device. The operation that includes the delivery of small amount of electrical stimulation to skeletal muscles for conditioning of the muscles.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device (21 CFR 807.92(a)(6)):

6.1. Technical characteristics

Parameter/application	E-Fit Infinity System	E-Fit EF-1280 (K133225)	Result
Powered Muscle Stimulator	YES	YES	same
Regulated	YES	YES	same
Output specification according to the Basic Unit characteristics document	Max Output Voltage = 37,2V @ 500 Ω	Max Output Voltage = 36 V @ 500 Ω	similar
	Max Output Current = 75mA @ 500 Ω	Max Output Current = 72 mA @ 500 Ω	similar
	Max Phase Charge = 26µC @ 500 Ω	Max Phase Charge = 36µC @ 500 Ω	similar
	Maximum Current Density = 0,9365 mA/cm2 @500 Ω	Maximum Current Density = 0,85 mA/cm2 @500 Ω	similar
	Maximum Power Density = 0,0342W/ cm2 @500 Ω	Maximum Power Density = 0.0063W/ cm2 @500 Ω	similar
Maximum Output Current	75mA (peak)/ 2.975mA (r.m.s.)	72 mA(peak)	similar
Maximum Output Voltage	0-48V	0-36V	similar
Number of channels	1 output channel can shift in time between the 12 outputs and electrical current can be regulated individually on every	1 output channel can shift in time between the 12 outputs and electrical current can be regulated individually on every output	same multichannel method

	output		
Waveforms	Symmetric biphasic	Symmetric biphasic	same
Output frequency	4-90 Hz	5-120 Hz	similar
Positive pulse width	100-500µsec	100-500µsec	same
Negative pulse width	100-500µsec	100-500µsec	same
Number of programs	6+93	5+5	new device has larger memory to store customer programs, the default programs are the same as predicate device
Program duration	Maximum 30 min.	Maximum 30 min.	same
Power source – Battery	2x 3,7V (3,2Ah) Li-PO, tested by IEC62133 and UN38.3	12V (3,4Ah) lead Acid	similar low voltage batteries
Size of the electrodes	Electrodes with pre-defined (supplied with the device) site and correct position.	Electrodes with pre-defined (supplied with the device) site and correct position.	same
User interface	The wireless controller has rotary encoder which 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 shutdown. Because of the pictographs on the displays and fixed electrodes in the clothing, it is very easy to set the appropriate muscle	The wired controller has rotary encoder which 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 shutdown. Because of the pictographs and fixed electrodes in the clothing, it is very easy to set the appropriate muscle groups.	Our older device which we want to use as a predicate device has wired controller, while the new device has a wireless controller. All the functions and control encoders are the same. The unit has the same physical buttons as the older predicate device. The

	groups.		user has an additional emergency power-off button next to his hand, plus there are no long remote controller cables around during training, so the new construction is safer.
Safety circuits	Short-circuit monitoring, watchdog monitoring, no load trip, onload trip, battery monitoring, battery voltage monitoring, output current monitoring (emergency STOP option), option for self- test, hardware error monitoring.	Short-circuit monitoring, watchdog monitoring, no load trip, onload trip, battery monitoring, battery voltage monitoring, output current monitoring (emergency STOP option), option for self-test, hardware error monitoring.	same
Portability/Mobile Use	Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator.	Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator.	same
Material of the enclosure	Polyamide and carbon fiber	Stainless steel	Different housing material. However, both devices have been successfully tested according to the relevant recognized safety standards (IEC60601)

Intended use	EF Infinity is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.	EF 1280 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.	same
Operator	By manufacturer 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.	By manufacturer 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.	same
Menu/Settings	Simple one-level menu system	Simple one-level menu system	same
Plug	Cables connect to the electrodes with snap fastener and connect to the machine with plastic connector.	Cables connect to the electrodes with snap fastener and connect to the machine with plastic connector.	same
Lead wires - cables	SIFF 0.5-1.5mm2 (1x375 unique filaments) ultra-flexible - Compliant with protected lead wire and patient cable safety requirements.	SIFF 0.5-1.5mm2 (1x375 unique filaments) ultra-flexible - Compliant with protected lead wire and patient cable safety requirements.	same
Conductivity of the electrodes	The subject needs to put on a 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	The subject needs to put on a 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	same

	conductive pads are washable and disinfectable.	efficiency will not decrease. The small conductive pads are washable and disinfectable.	
Soldering of the printed Circuit Boards	According to the ROHS directive there is no lead solder material used.	According to the ROHS directive there is no lead solder material used.	same
Placement of the electrodes	Appropriately pre-placed in specific areas according to muscle anatomy.	Appropriately pre-placed in specific areas according to muscle anatomy.	same
Reusable pads	YES	YES	same
Display	EF100: 3.5" TFT display EF-2090: 10" Touch screen TFT display	LCD 2*40 characters LCD display with LED backlight	different, new devices have a larger and higher resolution display.
Statistical functions	statistical functions – counting the hours of operation	statistical functions – counting the hours of operation	same

6.2. Summary of Testing and Comparison to the Predicate Device

E-Fit Infinity System and the predicate device have the same indications for use and very similar technological characteristics and features. E-Fit Infinity System has a wireless remote controller instead of long wired connection and this solution is better as a safe peer-to peer communication and avoids ESD phenomena (static discharge). Accidents due to the long cable during the therapy (movements, exercises) are eliminated. The ME device (EF-100) has all the necessary features to be a stand-alone device in itself: user interface, emergency stop button, indicator LEDs, display to show the treatment parameters.

There are a few design differences between the E-Fit Infinity System and the predicate device. However, these differences do not raise new questions for safety or efficacy. Specifically, the only technological difference between the E-Fit Infinity System and its predicate is the shape and material of the stimulator, and the user interface (larger display). These differences do not present any new issues in safety or effectiveness, as the E-Fit Infinity System is substantially similar to the predicate device. Concerns of safe and proper use of electrodes and electrode pad placement have been fully addressed by making the user

conscious of the proper placement of the electrodes and proper operation of the device through details in the User's Instruction Manual. The electrodes and structure of the technical wear is the same as the predicate device. The device's safety and effectiveness has improved via the educated trainer/operator's proper treatment skill. We guarantee that there are no new safety or effectiveness issues concerning this device to be introduced. The new device design method and design changes are recorded and performed according to the quality management system (ISO 13485, FDA 21 CFR 820.30).

The safety of the device, to be used for the proposed indications without medical prescriptions or supervision, is established by the fact that no adverse events have ever been reported since 2010 after over 6 million trainings on devices all over the world manufactured by Fit-Pro Ltd, using a platform equivalent to the predicate device, without a prescription. Over 60,000 trainings - from the 6 million - took place by using E-Fit Infinity System worldwide. The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrate that electrical stimulation does improve muscle performance and condition.

The new device is designed and manufactured in accordance with the latest international standards.

6.3. Conclusion of Substantial Equivalence

The E-Fit Infinity System was designed, manufactured and tested in the same factory as the predicate device under the same conditions according to the relevant standards and quality management system. All design, testing and manufacturing processes are recorded and validated according to the required FDA and ISO regulations. The device has the same intent of use and same indications and contraindications. All the accessories {patient cables and electrodes) are similar.

There are no differences which can raise any new issues regarding safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device