DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 24, 2014

Fit-Pro KFT Ltd.
C/O Ms. Rhonda Alexander
Senior Regulatory Specialist
Registrar Corporation
Medical Device Division
144 Research Drive
Hampton, VA 23666

Re: K133225
Trade Name: E-Fit EF-1280
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX, GXY
Dated: September 23, 2014
Received: September 25, 2014

Dear Ms. Alexander:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133225

Device Name
E-Fit EF-1280

Indications for Use *(Describe)*
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 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, and 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 EF-1280 can impose 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (21 CFR 807.92)

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

The assigned 510(k) number is: _____

Premarket Notification [510(k)] Summary

A. **General Information**

B. Submitter's Name: FIT PRO, LLC
Address: Sztregova Utca 22-28
Budapest, Pest 1116
Hungary
Telephone: +36-30-477-2460
Contact Person: Janos Papp, Managing Director
Date Prepared: 17 June 2013

C. Device

Trade Name: E-Fit EF-1280
Common Name: Stimulator, Muscle, Powered
Product Code: NGX
Class: 2
Regulation Number: 21 CFR 890.5850

D. Identification of Legally Marketed Predicate Device

The following predicate device has been identified:
Name: Compex Sport
Manufacturer: Compex S.A.
K Number: K011880

E. Description of the Device

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 muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes.

F. Intended Use

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 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 session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that the E-Fit EF-1280 can impose 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.

G. Technology characteristics

Parameter/application	E-Fit EF-1280	Compex Sport (K011880)
Powered Muscle Stimulator	YES	YES
Regulated	YES	YES
Output specification according the *Basic Unit characteristics document*	Max Output Voltage = 36 V @500Ω	Max Output Voltage = 48 V @500Ω
	Max Output Current = 72 mA @500Ω	Max Output Current = 96,1 mA @500Ω
	Max Phase Charge = 36µC @500Ω	Max Phase Charge = 32,3µC @500Ω
	Max Current Density = 0,85mA/cm2 @500Ω	Max Current Density = 3,84mA/cm2 @500Ω
	Max Power Density = 6,3mW/cm2 @500Ω	Max Power Density = 10,2mW/cm2 @500Ω
Maximum Output Current	72 mA	120 mA
Maximum Output Voltage	0-36V	0-135V

Number of channels	**1 output channel can shift in time to the 12 outputs but electrical current can be regulated individually on every outputs**	**4 independent channels which electrical current can be regulated individually**
Waveform	**symmetric biphasic**	**symmetric biphasic**
Output frequency	**5-120Hz**	**5-120Hz**
Positive pulse width	**100-500usec**	**50-400usec**
Negative pulse width	**100-500usec**	**50-400usec**
Number of programs	**5+5**	**4+5**

Program duration	**Maximum 30 min**	**Maximum 60 min**
Power source - Battery	**12V (3,4Ah) lead Acid**	**7,2V (1,2Ah) NIMH battery**
Size of the electrodes	**Electrodes with pre-defined (supplied with the device) size and correct position.**	**The choice of the size, the connection and the correct positioning of the electrodes are essential factors for ensuring effective and comfortable stimulation. So they require particular care.**
User interface	**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 shutdown. Because of the pictographs and fixed electrodes in the clothing, it is very easy to**	**The menu is complicated because of the slow integrated buttons. One button is responsible for more than one function and options.**

	set the appropriate muscle groups.	
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	no load trip, onload trip, battery monitoring
Portability/Mobile Use	Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator.	Small, portable device (pocket size)
Material of the enclosure	stainless steel	plastic
Intended use	EF 1280 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.	Compex Sport (K011880) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

Operator	**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.**	**Anyone can purchase and use the device on themselves with no technical assistance or security.**
Menu / Settings	**simple one-level menu system**	**more levels/sub-menus, complex menu system**
Plugs	**cables connect to the electrodes with snap fastener and connect to the machine with plastic 12pin waterproof ip68 connector.**	**cables connect to the electrodes with snap fastener and connect to the machine with 4 similar plastic 2pin connector. the similar interchangeable connectors are increase the risk of undefined channel control**
Lead wires - cables	***SIFF 1-1.5mm2 (1x375 unique filaments)ultra flexible* - Compliant with protected lead wire and patient cable safety requirements**	***CU 0,2mm2 (1x50 unique filaments) partly flexible* - Compliant with protected lead wire and patient cable safety requirements**
Conductivity of the electrodes	**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**	**Limited usage, gel-covered electrodes. After some usage, the quality of the electrodes, resistance and adherence will depend on the user's skin type.**

	case the pulse transmission efficiency will not decrease. The small conductive pads are washable and disinfect able.	
Soldering of the Printed Circuit Boards	**According to the ROHS directive there is no lead solder material used**	**Lead soldering solutions**
Placement of the electrodes	**Appropriately pre-placed in specific areas according to muscle anatomy.**	**Self-Adhesive on any area of body.**
Reusable pads	**YES**	**YES**
Display	**LCD 2x40 character LCD display with LED backlight**	**LCD graphical display**
Statistical functions	**statistical functions - counting the hours of operation**	**NO**

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

H. Summary of Testing and Comparison to the Predicate Device

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

- EN ISO 14971:2012
- EN ISO 13485:2003 /AC2009
- IEC 60601-1:2005 3rd edition
- IEC 60601-1-2:2007
- IEC 60601-1-11:2010
- IEC 60601-2-10:2012

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

Compared the E-Fit EF 1280 to the predicate device, Compex Sport (K011880) it can be established that the E-Fit EF-1280 is similar in intended use, performance, design,

dimensions, and materials as the predicate device. The new device meets the same standards for safety as the predicate device.

I. Conclusion of Substantial Equivalence

Based on the comparison of intended use, design, materials and performance we conclude that the new device is substantially equivalent to the predicate devices in all aspects impacting on safety and effectiveness.

The differences that exist between the devices do not raise new issues of safety or effectiveness.