January 22, 2020

Fast Fit LLC
% Sigi Caron
Regulatory Consultant
Biologics and Medical Device Consulting Group
20370 Skyhawk Lane
Topanga, CA 90290

Re: K192161
Trade/Device Name: FastFit EMS System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 24, 2019
Received: October 24, 2019

Dear Sigi Caron:

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 Vivek Pinto, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192161

Device Name
FastFit EMS System

Indications for Use *(Describe)*
The FastFit EMS System is intended to simulate healthy muscles in order to improve or facilitate muscle performance.

It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the stimulation programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated.

The FastFit EMS System is Rx only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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."

1. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE PREPARED	August 6, 2019
APPLICANT	Fast Fit LLC 450 Park Avenue 31st Floor New York, NY 10022
OFFICIAL CORRESPONDENT	Sigi Caron, MBA RAC Biologics and Medical Device Consulting Group 20370 Skyhawk Lane Topanga, CA 90290 Tel: (310) 455-3473 Fax: (888) 295-1535 sigi@BioMDG.com
TRADE NAME	FastFit EMS System
COMMON NAME	Stimulator, Muscle Powered, for Muscle Conditioning
DEVICE CLASSIFICATION	Name: Powered Muscle Stimulator Regulation No: 21 CFR §890.5850 Product Code: NGX – Stimulator, Muscle Powered, for Muscle Conditioning Class: II
PREDICATE DEVICE	Compex® Wireless USA (K143551) Katalyst Mark 1 Muscle Stimulation System (K181199)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The EMS System is a series of electrical muscle stimulation (EMS) electrodes embedded in a compression textile body suit intended to be worn by a user during physical exercise. When operated, the device provides localized electrical muscle stimulation (EMS) pulses to major muscle groups at controllable intensities. When operated, the device provides localized EMS pulses to major muscle groups at controllable intensities. The FastFit EMS system consists of the following primary components:

- FastFit Exercise Suit
- EMS Controller
- Power Adaptor
- FastFit Software Application

The FastFit Exercise Suit is a full body compression garment made from a Nylon/Spandex stretch fabric that incorporates embedded electrodes over key muscle groups. These electrodes are constructed of a conductive fabric sewn over a foam pad. Each electrode is connected via an integrated set of wiring leads sewn into the suit fabric that connect to a central contact pad at the right hip of the suit. A suit-to-controller connector at the central contact pad has 10 pairs of pins that act as lead contacts. Once connected to the suit, the EMS controller can deliver EMS pulses at the programmed intervals.

EMS pulse intensity and target locations are controlled via a Bluetooth connection with a user's smartphone installed with the FastFit software application. A graphic user interface displayed on the touchscreen of the smartphone allows for the user to customize the stimulation program parameters at their discretion. After stimulation parameters have been set by the user with the software application, the parameters are uploaded to the EMS controller, and stimulation can be started anytime at the discretion of the user. The EMS controller is powered by a rechargeable lithium ion battery. A separate with an AC power adapter is provided to recharge the EMS controller when not in use.

INDICATIONS FOR USE:

The FastFit EMS System is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the stimulation programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated.

The FastFit EMS System is Rx only.

SUBSTANTIALLY EQUIVALENT TO:

The FastFit EMS System is substantially equivalent in intended use and technological features to two other commercially available powered muscle stimulator systems:

- Compex® Wireless USA (K143551)
- Katalyst Mark 1 Muscle Stimulation System Model 2 (K181199)

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The FastFit EMS system is substantially equivalent to the listed predicate devices with respect to their indications for use (intended use) and technical characteristics. The following table compares the features of the proposed device and its predicates.

Element	New Device: FastFit EMS System	Primary Predicate: Compex Wireless USA	Secondary Predicate: Katalyst Mark 1 Muscle Stimulation System Model 2
510(k) Number	-----	K143551	K181199
Indications for Use	The FastFit EMS system "***is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.*** ***It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind."*** None of the stimulation programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated." The FastFit EMS system is Rx only.	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. 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 electrical impulses allow the triggering of action potentials 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 simulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.	The Katalyst Mark 1 "***is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.*** ***It is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind."*** None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated." The Katalyst Mark 1 is Rx only.

Element	New Device: FastFit EMS System	Primary Predicate: Compex Wireless USA	Secondary Predicate: Katalyst Mark 1 Muscle Stimulation System Model 2
Device Features			
Connection of device to electrodes	The EMS controller is connected via a cable electrode harness directly to the electrode pads.	Stimulation Module is directly connected to the custom Compex female SNAP assembled in the electrode.	The Katalyst Impulse Pack unit is connected via a cable electrode harness directly to the electrodes.
Power Source	EMS Controller Module: Rechargeable 3.7[V] / ≥ 1800[mAh] LiPo battery	Remote: : Rechargeable 3.7[V] / ≥ 1500[mAh] LiPo battery Stimulation Modules: Rechargeable 3.7[V] / ≥ 450[mAh] LiPo battery	Li-Po rechargeable battery 3.8V, 7.79Wh (2050mAh)
Charging System	AC/DC 5[v] 2.0 [A]; Distributed through docking station	AC/DC 5[v] 3.5[A]; Distributed through docking station to remote and 4 modules	AC/DC wall plug in, distributed directly to the device. 18.0[v], 1.33[A]
Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)
Patient Leakage Current **-Normal Condition** **-Single Fault Condition**	N/A (battery operated device)	N/A (battery operated device)	N/A (battery operated device)
Number of Output Modes	One (NMES)	One (NMES)	One
Number of Output Channels **-Synchronous or alternating?**	10 alternating (never 2 channels activated at the same time)	4 Synchronous, but never 2 channels activated at the same time	10 Not publicly available
Method of Channel Isolation	Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state.	Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state.	Not publicly available
Regulated Current or Regulated Voltage?	Regulated current (all channels)	Regulated current (all channels)	Not publicly available
Electrode Integrated into a body suit?	Yes	No. Placement of electrodes is dictated by the operator.	Yes
Number of Electrodes	2 per channel, 4 per channel on each arm and on each leg; Max 20	Not publicly available	Only 2 per channel; Max 20

Element	New Device: FastFit EMS System	Primary Predicate: Compex Wireless USA	Secondary Predicate: Katalyst Mark 1 Muscle Stimulation System Model 2
Electrode Leads Compliant with 21 CFR 898?	Yes	Yes	Yes
Electrode Interface	10mm magnetic buttons	Not publicly available	4mm Standard SNAP Connector
Wireless Communication with Control Interface	Yes. Uses Bluetooth Smart (BT LE 4.0)	Not publicly available	Yes. Uses Bluetooth Smart (BT LE 4.0)
Mobile / Form Factor	Yes (smartphone, stim device attached to suit, and wearable suit)	Not publicly available	Portable with difficulty, no mobile device, its intended use requires a Katalyst certified operator.
Channel Control Interface	Touch user interface provided by FastFit application on smartphone.	Not publicly available	Using rotary encoder knobs for each channel and master rotary encoder for all channels
Instant Shutoff	Physical Button	Not publicly available	Physical Button
Software / Firmware / Microprocessor Control?	Yes	Yes	Yes
Automatic Overload Trip?	Yes	Yes	Yes
Automatic No-Load Trip?	No	Yes	No
Automatic Shutoff?	Yes	Yes	Yes
Patient Override Control?	Yes	Yes	No
Interface Indicator Display: **-On/Off Status**	Yes (on remote and module units)	Yes	Yes (on Impulse Pack via LED and in application)
-Low Battery	Yes	Yes	Yes (on Impulse Pack)
-Voltage/Current Level	Yes (on smartphone)	Yes	Yes (in application)
-Charging	Yes	Yes	Yes (on Impulse Pack)
-Duration of training	Yes (on smartphone)	Yes	Yes (in application)
Timer Range in Minutes	Maximum = 120 minutes	Maximum = 48 minutes	Maximum = 20 minutes
Weight	Controller Module: 505 g EMS Suit: 695 g	Remote: 119 g Stimulation Module: 2x60 g Docking Station: 800 grams	Not publicly available

Element	New Device: FastFit EMS System	Primary Predicate: Compex Wireless USA	Secondary Predicate: Katalyst Mark 1 Muscle Stimulation System Model 2
Dimensions	Controller Module: 11.7x8.9x4.8 cm	Remote: 9x4.5x0.7 cm Stimulation Module: 6.5x2 cm Docking Station: 25x25x2 cm	Not publicly available
Housing Materials and Construction	Nylon, Spandex Polyester w/ Conductive Coating	Not publicly available	Not publicly available
Output Specifications			
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic
Shape	Rectangular	Rectangular	Rectangular
Maximum Output Voltage (±10%)	35 V @500 Ω 95 V @ 2 kΩ 96 V @ 10 kΩ	60 V @ 500 Ω 180 V @ 2 kΩ 180 V @ 10 kΩ	60 V @ 500 Ω 96 V @ 2 kΩ 114.2 V @ 10 kΩ
Maximum Output Current (±10%)	70 mA @500 Ω 47.5 mA @ 2 kΩ 9.6 mA @ 10 kΩ	120 mA @ 500 Ω 90 mA @ 2 kΩ 18 mA @ 10 kΩ	120 mA @ 500 Ω 48 mA @ 2 kΩ 11 mA @ 10 kΩ
Pulse Width	300 µs	300 to 400 µs	175 µs
Frequency	84 Hz	1 to 120 Hz	85 Hz
For multiphasic waveforms only: **-Symmetrical phases?** **-Phase Duration (include units)(state range, if applicable)(both phases, if asymmetrical)**	Yes. Symmetrical, 300 µs	Yes Symmetrical, 300 - 400 µs	Yes Symmetrical, 175 µs
Net Charge [µC/Pulse]	0 [µC] @ 500Ω Excitation pulse fully compensated	0 [µC] @ 500Ω Excitation pulse fully compensated	0.5 [µC] @ 500Ω Excitation pulse fully compensated
Maximum Phase Charge [µC]	21 [µC] @ 500Ω	48 [µC] @ 500Ω	21 [µC] @ 500Ω
Maximum Current (RMS) Density [mA/cm2]	0.032 mA/cm2 @ 500Ω	1.49 mA/cm^2 @ 500Ω	0.788 mA/cm^2 @ 500Ω
Maximum Power Density [mW/cm2]	1.25 mW/cm2 @ 500Ω	27.6 mW/cm^2 @ 500Ω	8.16 mW/cm^2 @ 500Ω

Element	New Device: FastFit EMS System	Primary Predicate: Compex Wireless USA	Secondary Predicate: Katalyst Mark 1 Muscle Stimulation System Model 2
Burst Mode	N/A	Not publicly available	N/A
ON Time	4 second intervals	Not publicly available	4 second intervals
OFF Time	4 second intervals	Not publicly available	4 second intervals

SUMMARY OF SIMILARITIES / DIFFERENCES:

The FastFit EMS system provides localized electrical muscle stimulation (EMS) pulses to major muscle groups at controllable intensities in the same way as both the predicate devices. All three devices are intended to be used in addition to physical exercise to stimulate healthy muscles in order to improve or facilitate muscle performance. The same fundamental technology platform is employed by all three devices. These devices are all comprised of a set of electrodes powered by a portable battery pack that can deliver an electrical stimulation that is adjustable by the user through a wireless remote user interface. The FastFit EMS system and the Katalyst Mark I both have their electrodes integrated into a wearable body suit, whereas the Compex® Wireless USA allows for each electrode to be independently positioned at the users' discretion.

One notable difference between the FastFit EMS system and the predicate devices is that the FastFit EMS delivers EMS with a much lower maximum current density and power density. This can be accomplished because the FastFit EMS system uses a larger electrode surface area and a lower duty cycle. A lower maximum current and power density for the FastFit represents a lower risk to the user in comparison to the predicate devices.

Another notable difference is in the interface application. The FastFit EMS uses a software application that downloads onto a mobile device (such as a smartphone), whereas the Compex® Wireless uses a software application installed on a proprietary remote device and the Katalyst Mark I uses a software application on a commercially available tablet (Microsoft Surface). Although a few other minor differences exist between the subject and predicate devices (see Basis for Substantial Equivalence Table), these differences do not adversely impact the safety and effectiveness of the subject device.

SUMMARY OF NONCLINICAL TESTING:

Comprehensive design verification and validation testing was performed on the FastFit EMS system. Results from bench and animal testing demonstrated that the function, performance, and safety of the device meet its intended use. Testing performed included a combination of the following:

- System Design Verification Testing
- Software Verification and Validation

- Electrical Safety Testing (IEC 60601-1, IEC 60601-1-11, IEC 60601-1-6, IEC 60601-2-10)
- Electromagnetic Compatibility Testing (IEC 60601-1-2)
- Biocompatibility Testing (ISO 10993-1, ISO 10993-5, and ISO 10993-10)
- Usability/Human Factors Testing

Overall, testing confirmed that the FastFit EMS system can be used according to its intended use and in an equivalent manner to the predicate device.

CONCLUSION:

The information and data provided in this 510(k) submission identifies no new safety or effectiveness issues. Based on the above information, FastFit believes that the substantial equivalence of the FastFit EMS system to the Compex Wireless USA and Katalyst Mark 1 has been demonstrated.