April 5, 2019

XBody Hungary Kft.
℅ R. William Soller
President
Biomedical Regulatory Consulting
9203 Hwy 6 South, Suite 124
Houston, Texas 77083

Re: K190038
Trade/Device Name: Xbody Newave USA
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 1, 2018
Received: January 8, 2019

Dear R. William Soller:

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 J. Pinto -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)*
K190038

Device Name
XBODY NEWAVE USA

Indications for Use *(Describe)*
The XBODY NEWAVE USA is a machine with electronic muscle stimulation based on EMS technology. The device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and people (clients), not for rehabilitation purposes.

The XBODY NEWAVE USA is intended to stimulate healthy muscles in order to improve or facilitate muscle performance The XBODY NEWAVE USA is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the XBODY NEWAVE USA training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

The XBODY NEWAVE USA 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 XBODY NEWAVE USA can impose on the stimulated muscles are able to improve or facilitate muscle performance. The XBODY NEWAVE USA 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.

Premarket Notification [510(k)] Summary

A. General Information

Sponsor's Name:	XBody Hungary Kft.
Sponsor's Contact Person:	Péter Tar Research & Development Manager
Address:	György Aladár u. 35-39 Budapest, Hungary 1125 peter.tar@xbodyworld.com www.xbodyworld.com
US Contact Person:	R. William Soller, PhD
Address:	Biomedical Regulatory Consulting 9203 Hwy 6 South, Suite 124 Houston, Texas 77083 CELL (713) 380-7146 FAX (888) 370-5065 rwsoller@biomedreg.com
Date Prepared:	October 1, 2018

B. Device

Trade Name:	XBODY NEWAVE USA
Common Name:	Stimulator, Muscle, Powered
Product Code:	NGX
Class:	2
Regulation Number:	21 CFR 890.5850

C. Identification of Legally Marketed Predicate Device

Name:	E-Fit EF-1280
Manufacturer:	FIT PRO, LLC
K Number:	K133225

D. Description of the Device

The XBODY NEWAVE USA is a machine with electronic muscle stimulation based on EMS technology. 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.

E. Indication for Use (Same as Predicate)

The XBODY NEWAVE USA is a machine with electronic muscle stimulation based on EMS technology. 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 XBODY NEWAVE USA is intended to stimulate healthy muscles in order to improve or facilitate muscle performance The XBODY NEWAVE USA is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the XBODY NEWAVE USA training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

The XBODY NEWAVE USA 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 XBODY NEWAVE USA can impose on the stimulated muscles are able to improve or facilitate muscle performance. The XBODY NEWAVE USA may therefore be considered a technique of muscle training.

F. Technological Characteristics

Compared the to the predicate device, XBODY NEWAVE USA 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.

Parameter / Application	**XBODY NEWAVE USA**	**E-Fit EF-1280, Predicate (K133225)**	**Assessment of Substantial Equivalence**
Powered Muscle Stimulator	Yes	Yes	Same
Regulated	Yes	Yes	Same
Output specification	Max Output Voltage = 30 V @500Ω	Max Output Voltage = 36 V @500Ω	Similar
	Max Output Current = 60 mA @500Ω	Max Output Current = 72 mA @500Ω	Similar
	Max Phase Charge = 24μC@500Ω	Max Phase Charge = 36μC @500Ω	Similar
	Max Current Density = 0.61mA/cm2 @500Ω	Max Current Density = 0.85mA/cm2 @500Ω	Similar
	Max Power Density = 7.27mW/cm2 @500Ω	Max Power Density = 6.3mW/cm2 @500Ω	Similar
Max Output Current	60 mA	72 mA	Similar
Max Output Voltage	50V	0-36V	Similar

Number of channels	10 individual, galvanically isolated channels for each output	1 output channel can shift in time to the 12 outputs but electrical current can be regulated individually on every output	Similar
Waveform	Symmetric biphasic	Symmetric biphasic	Same
Output frequency	1-100Hz	5-120Hz	Similar
Positive pulse width	50-400usec	100-500usec	Similar
Negative pulse width	50-400usec	100-500usec	Similar
Number of programs	4+10	5+5	Similar
Program durations	1 min to 60 min maximum	1 min to 30 min maximum	Similar
Power source - Battery	12V 10Ah LiFePO4 battery in sealed housing The battery is housed in the stand that contains the device control panel. The battery can only be charged if disconnected from the stand.	12V (3.4Ah) Lead Acid	Similar
Size of the electrodes	Predefined electrode sizes inside the training suit described in User Manual	Electrodes with pre-defined (supplied with the device) size and correct position.	Similar
User interface	The device can be controlled using graphical windows appearing on the touchscreen of the device. On the training screen where stimulation controls can be used the START/ STOP buttons are large and easily controllable. Stimulation controls for adjusting channel intensities, and all other stimulation parameters are clearly visible and easily controllable. Channel identification is supported with big pictures showing the selected muscle groups. When the stimulation is on, the STOP button is always visible and accessible.	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 complet epower shutdown. Because o f the pictographs and fixed electrodes in the clothing, it i svery easy to set the appropriate muscle groups.	Similar
Safety circuits	No load trip, overload trip detects short-circuit and circuit break, battery voltage	Short-circuit monitoring, watchdog monitoring, no load trip, onload trip,	Same

	monitoring hardware error detection at startup, and watchdog monitoring	battery monitoring, battery voltage monitoring, output current monitoring (emergency STOP option), option for self-test, hardware error monitoring	
Portability/Mobile Use	The device is portable (17 lbs), but it is not a mobile device. Its intended use requires presence of a qualified and trained operator.	The device is portable with difficulty. It is not a mobile device. Its intended use requires the qualified and trained operator.	Same
Material of the enclosure	Composite	Stainless steel	Similar
Intended use	The XBODY NEWAVE USA 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	To operate the device the trainer must complete an XBody Trainer Course. The certification data received at the end of the course is required when XBody registers trainers in the device database. Only registered trainers can start training stimulation programs using a passcode.	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.	Same
Menu / Settings	Easy-to-use multi-choice menu for registered and certified trainers to customize training parameters and stimulation programs.	Simple one-level menu system	Similar
Plugs	A spiral cable connects the device control unit to the training suit. The internal cable of the training suit connects to snap fasteners in the suit to which detachable electrodes are attached via waterproof connections.	Cables connect to the electrodes with snap fastener and connect to the machine with plastic 12pin waterproof ip68 connector.	Similar
Lead wires - cables	PVC coated ultra-flexible LIFY 0,50 mm2 (256 x 0,05 mm) cables and LiYV 0,56	*SIFF 1-1.5mm2 (1x375 unique filaments) ultra flexible* - Compliant with protected lead wire and	Similar

	mm2 (7 x 0,32 mm) in the training suit. Spiral cable with Li12Y11Y 25 x 0,14 mm2. Cables are compliant with protected lead wire and patient cable safety requirements	patient cable safety requirements	
Conductivity of the electrodes	The client has to wear an XBody cotton underwear (biocompatibility certified). The electrodes are contained in cotton covers which must be soaked/ irrigated using normal tap water to create conductive media. The cotton textiles holds enough water to provide conductivity during the training. The electrodes are washable and can be disinfected, as described in User Manual.	The subject needs to put on an 100% hygroscopic cotton underwear (surgery textile, biocompatibility certified) and these underwear need 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 pads are washable and can be disinfected	Same
Soldering of the Printed Circuit Boards	In accordance with the ROHS directive, no lead solder material used.	According to the ROHS directive there is no lead solder material used.	Same
Placement of the electrodes	The electrodes are located at fixed positions in the training suit ensuring proper placement.	Appropriately pre-placed in specific areas according to muscle anatomy.	Similar
Reusable pads	Yes	Yes	Same
Display	10.4” resistive touchscreen	LCD 2x40 character LCD display with LED backlight	Similar
Statistical Functions	Training data (trainer, client, date, duration). Number of trainings (today, yesterday, this week, this month, total).	Statistical functions – counting the hours of operation	Similar

The identified differences between subject and predicate devices are minimum. Output specifications of the subject device are similar to the predicate and meet the IEC safety requirements for powered muscle stimulators. Stimulation parameters are similar, allowing substantially equivalent muscle work to be achieved by the subject device. The subject device provides channel isolation galvanically which ensures that each pair of electrodes

define proper current path in the body. Hence, the XBody choice of existing technology is substantially equivalent to time shifting used by the predicate. LiFePo4 batteries of the XBody device have a longer cycle-life and are more durable than Lead Acid batteries used by the predicate. The menu and the user interface of both devices are similar, easily operable and therefore known to the operators. Statistic reports from XBody NEWAVE USA are more detailed than the predicate, to enhance usability. The material of XBody stand and enclosure is made of durable composite, with similar function of the predicate.

G. Summary of Testing and Comparison to the Predicate Device

XBODY NEWAVE USA is designed and manufactured in accordance with the application of the following standards and FDA guidances.

Standard Number	Applied Standards by Title	FDA Recognition Number
ANSI/AAMI 60601-1:2005/ (R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2:2007.	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8
IEC 60601-1-6:2010 (Third Edition) + A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 60601-1-11:2015	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	19-14
IEC 60601-2-10:2007 + AMD1 2012.	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	17-16
IEC 62366:2007 + A1: 2014.	Medical devices – Application of usability engineering to medical devices	5-114
ASTM-F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	14-497
ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process. (Biocompatibility)	2-156
ISO 10993-5	Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity.	2-153
ISO 10993-10	Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization.	2-173
ISTA 3E	General simulation test for unitized loads of the same retail or institutional packaged-product	5-112
EN ISO 14971:2012.	Medical devices - Application of risk management to medical devices.	5-40

EN ISO 13485:2003 /AC2009	Medical Devices – Quality Management Systems – requirements for regulatory purposes	N/A
Applied Guidances		
FDA Guidance	Food and Drug Administration Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices 2005	N/A
FDA Guidance	Guidance for Industry, FDA Reviewers/Staff and Compliance Guidance Document for Powered Muscle Stimulator 510(k)s, June 9, 1999	N/A
FDA Guidance for Industry and FDA Staff:	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"	N/A

H. Conclusion

XBODY NEWAVE USA does not use any new technology. Differences between the subject device and its predicate are minimum and do not affect safety and effectiveness (SE). The general information for the new device and the predicate is the same in terms of intended use, indications and principles of operation. There are minimum differences in the technological characteristics and performance data for the new device and the predicate; however, both devices comply with the IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-10 standards. Thus, these differences do not affect substantial equivalence between the devices.

Conclusion: XBODY NEWAVE USA is substantially equivalent to the predicate device.

END OF DOCUMENT.