January 31, 2023

XBody Hungary Kft.
% Bhoomika Joyappa
Associate Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd
Shrewsbury, Vermont 05738

Re: K221200
Trade/Device Name: XBody Go USA, XBody Pro USA
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 17, 2023
Received: January 17, 2023

Dear Bhoomika Joyappa:

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,

Tushar Bansal -S

for Heather Dean, PhD
Acting 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)*
K221200

Device Name
XBODY Go USA and XBODY Pro USA

Indications for Use *(Describe)*
The XBODY Go USA and XBODY Pro 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 Go USA and XBODY Pro USA is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The XBODY Go USA and XBODY Pro 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 Go USA and XBODY Pro USA training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.
The XBODY Go USA and XBODY Pro 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 Go USA and XBODY Pro USA can impose on the stimulated muscles are able to improve or facilitate muscle performance. The XBODY Go USA and XBODY Pro 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.

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Premarket Notification [510(k) Summary]
K221200

A. General Information

Sponsor's Name:	XBody Hungary Kft.
Sponsor's Contact Person:	Orsolya Balog (Regulatory Compliance)
Address:	György Aladár u. 35-39 Budapest, Hungary 1125 orsolya.balog@XBodyworld.com www.XBodyworld.com
Phone	+36308970191
Submission Contact Person:	Bhoomika Joyappa
Address:	Associate Regulatory Consultant Medical Device Academy, Inc **bhoomika@fdaecopy.com** 345 Lincoln Hill Rd, Shrewsbury, VT 05738
Phone	+1.201-290-2613
Date Prepared:	April 4, 2022

B. Device

Trade Names of Companion Products:	XBody Go USA, XBody Pro USA
Common Name:	Powered Muscle Stimulator
Product Classification Code:	NGX
Regulatory Class:	2
Device Classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850

C. Identification of Legally Marketed Primary Predicate Device and Reference Device

Primary Predicate Device:	XBody Newave USA
Manufacturer:	XBody Hungary Kft
Predicate 510(k) Number:	K190038
Reference Device:	WiemsPro
Manufacturer:	Medical Cables, S.L.
Reference 510(K) Number:	K181955

D. Description of the Devices

The XBody Go USA and the XBody Pro USA generate electronic muscle stimulation based on EMS technology. The devices are designed as additions to other sports and for training muscles. They are not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. They are intended for use only by persons with healthy muscles, not for rehabilitation purposes.

E. Indication for Use

The XBody Go USA and XBody Pro USA are machines with electronic muscle stimulation based on EMS technology. The devices are specifically designed as an addition to other sports and for training muscles. They must be used for only healthy muscles and clients, not for rehabilitation purposes.
Both models are intended to stimulate healthy muscles in order to improve or facilitate muscle performance. Neither model is intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the XBody Go USA or XBody Pro USA training programs are designed for injured or ailing muscles and its use on such muscles is contraindicated.
For both models, 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 Go USA and XBody Pro USA can impose on the stimulated muscles are able to improve or facilitate muscle performance. Both models may therefore be considered a technique of muscle training.

F. Technological Characteristics

Compared to the primary predicate device, the XBody Go USA and XBody Pro USA are the same or similar in indication for use, intended use performance, design, dimensions, and materials as the primary predicate and reference devices. The new devices meet the same standards for safety and performance as the primary predicate and reference devices.

The differences cited in the comparison tables between subject, primary predicate and reference devices do not affect safety and performance of the subject devices when compared for equivalence to the primary predicate and reference devices. Where there is not publicly available information for a comparison between the two subject devices (XBody Go USA and XBody Pro USA) and one of the predicates (WiemsPro) in Table 1 and 3, this application relies on the comparison of the subject devices to XBody Newave USA. This is noted where appropriate as "No information publicly available."
Comment on WiemsPro. This reference device is used for its wireless attributes for comparison to XBody subject devices.

Table 1
Comparison of Subject Devices (XBody Go USA and XBody Pro USA) to Predicate and Reference Devices: General and Electrical Parameters

Parameter / application	Subject Device XBody Go USA and XBody Pro USA (K221200)	Primary Predicate XBODY Newave USA (K190038)	Reference Device WiemsPro (K181955)	Assessment of Substantial Equivalence	
				XB Go USA & XB Pro USA vs. XB Newave USA	XB Go USA & XB Pro USA vs. WiemsPro
Powered Muscle Stimulator	Yes	Yes	Yes	Same	Same
Regulated voltage	Yes	Yes	Yes	Same	Same
Intended use	The XBody Go USA and XBody Pro USA are machines with electronic muscle stimulation based on EMS technology. The devices are specifically designed as an addition to other sports and for training muscles. They must be used for only healthy muscles and people	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	WiemsPro is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The WiemsPro is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of WiemsPro training programs is designed for injured or ailing muscles and its use on such muscles	Same	Same

	(clients), not for rehabilitation purposes. The XBody Go USA and XBody Pro USA are intended to stimulate healthy muscles in order to improve or facilitate muscle performance The XBody Go USA and XBody Pro USA are not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the XBody Go USA or XBody Pro USA training programs are designed for injured or ailing muscles and its use on such muscles is contraindicated. The XBody electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of	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 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	is contraindicated. WiemsPro 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. WiemsPro 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		

	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 Go USA or XBody Pro USA can impose on the stimulated muscles are able to improve or facilitate muscle performance. The XBody Go USA and the XBody Pro USA may therefore be considered as a technique of	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.	work can be imposed on the stimulated muscles.		

	muscle training.				
Portability/ Mobile Use	The device is portable with ease. It is not a mobile device; its intended environment is indoors. Its intended use requires a qualified and trained operator.	The device is portable (17 lbs.), but it is not a mobile device. Its intended use requires the presence of a qualified and trained operator.	No information publicly available	Similar. Both the primary predicate device and the subject devices are portable.	N/A
Go out Mode	Present	Not available	No information publicly available	This is an additional upgrade to the device's functionality. The impact of the Go out mode on safety and effectiveness was evaluated through risk management. In Go out mode, you have a lot of freedom and flexibility to customize your training, so it is an exceptionally useful feature. With the issued risk control measures, safety of the Go out mode is ensured. Users are provided with comprehensive information in user manuals for the device before using it during training, reducing the risk of accidents	N/A
User interface	The device can be controlled using the graphical windows appearing on the touchscreen of the external control unit (Microsoft Surface	The device can be controlled using the graphical windows appearing on the touchscreen of the device. On the training screen where stimulation	No information publicly available	Similar. Both the primary predicate device and the subject devices utilize a device with touchscreen as control unit.	N/A

	Go 2 for XBody Go USA / Microsoft Surface Pro 7+ for XBody Pro USA). 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.	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.			
Menu / Settings	Easy-to-use multi-choice menu for registered and certified trainers to customize training parameters and stimulation Programs.	Easy-to-use multi-choice menu for registered and certified trainers to customize training parameters and stimulationPrograms.	No information publicly available	Same	N/A

Operator	To operate the devices the trainer must complete an XBody US EMS 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.	To operate the device the trainer must complete an XBody US EMS 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.	No information publicly available	Same	N/A
Display	GO: <10.5" LCD display on the XBody Go USA tablet> PRO: <12.3" LCD display on the XBody Pro USA tablet >	10.4" resistive touchscreen	No information publicly available	Different. Subject devices have bigger screens with capacitive LCD touch screens providing more accurate touch reading	Similar
Statistical Functions	Training data (trainer, client,date, duration). Client related data. Number of training sessions (today, yesterday, this week, this month, total).	Training data (trainer, client,date, duration). Client related data. Number of training sessions (today,yesterday, this week, this month, total).	No information publicly available	Same	N/A
Output specifications	Max Output Voltage = 20.8V @500Ω	Max Output Voltage = 30V @500Ω	Max Output Voltage = 62.5V @500Ω	Similar. Subject devices have lower max output voltage. This particular feature has already been tested to IEC	Different. Subject devices have lower max output voltage. This particular feature has already been tested to IEC

				60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.	60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.
	Max Output Current = 41.6mA @500Ω	Max Output Current =60 mA @500Ω	Max Output Current = 125mA @500Ω	Similar. Subject devices have lower max output current. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.	Different. Subject devices have lower max output current. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.
	Max Phase Charge = 16.64µC@500Ω	Max Phase Charge = 24µC@500Ω	No information publicly available	Similar. Subject devices have lower max phase charge. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.	N/A
	Max Current Density = 0.65mA/cm2 @500Ω	Max Current Density = 0.61mA/cm2 @500Ω	Max Current Density =1.92mA/cm2 @500Ω	Similar. Subject devices have lower max current density. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.	Different. Subject devices have lower max current density. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and effectiveness.
	Max Power Density =3.46mW/cm2 @500Ω	Max Power Density = 7.27mW/cm2 @500Ω	Max Power Density = 9.61mW/cm2 @500Ω	Similar. Subject devices have lower max power density. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and	Different. Subject devices have lower max power density. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. This difference does not raise any concern for safety and

				effectiveness.	effectiveness.
Net Charge (µC per pulse)	0 @500Ω (each phase uses symmetric waveform)	0 @500Ω (each phase uses symmetric waveform)	Information Not Available	Same	N/A
Shape	Rectangular	Rectangular	Rectangular	Same	Same
Number of Output channels	6 output channels, but 12 independently regulated outputs	10 individual, galvanically isolated channels for each output	1 output channel can shift intime to 10 outputs, but electrical current can be regulated individually on every output	Similar	Different. Subject devices have more independently regulated output channels.
Waveform	Symmetric biphasic	Symmetric biphasic	Symmetric biphasic	Same	Same
Burst mode - Pulses per burst	100 * 10 = 1000	100 * 10 = 1000	Information Not Available	Same	N/A
Burst mode - Bursts per second	0.1	0.1	Information Not Available	Same	N/A
Burst mode - Burst duration (seconds)	11	11	Information Not Available	Same	N/A
Burst mode - ON Time (seconds)	10	10	Information Not Available	Same	N/A
Burst mode - OFF Time (seconds)	1	1	Information Not Available	Same	N/A
Burst mode - Duty Cycle: Line (d)/(Line (d)+ Line (e))*	0.91	0.91	Information Not Available	Same	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A	N/A
Output frequency	1-150Hz	1-100Hz	1-100Hz	Different. Object devices provide better customization through a wider spectrum of output	Different. Object devices provide better customization through a wider spectrum of output

				frequency. During the summative evaluation, the users evaluated the feeling of stimulation positively. The main output parameters (output current and output voltage) are lower for the subject devices than for the primary predicate and reference device. Therefore, the difference would not affect safety and effectiveness of the subject device.	frequency. During the summative evaluation, the users evaluated the feeling of stimulation positively. The main output parameters (output current and output voltage) are lower for the subject devices than for the primary predicate and reference device. Therefore, the difference would not affect safety and effectiveness of the subject device.
Positive pulse width	50-500usec	50-400usec	100-400usec	Different. Object devices provide better customization through a wider spectrum of positive pulse width. During the summative evaluation, the users evaluated the feeling of stimulation positively. The main output parameters (output current and output voltage) are lower for the subject devices than for the primary predicate and reference device. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. Therefore, the difference would not affect safety and effectiveness of the subject device.	Different. Object devices provide better customization through a wider spectrum of positive pulse width. During the summative evaluation, the users evaluated the feeling of stimulation positively. The main output parameters (output current and output voltage) are lower for the subject devices than for the primary predicate and reference device. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. Therefore, the difference would not affect safety and effectiveness of the subject device.

Negative pulse width	50-500usec	50-400usec	100-400usec	Different. Object devices provide better customization through a wider spectrum of negative pulse width. During the summative evaluation, the users evaluated the feeling of stimulation positively. The main output parameters (output current and output voltage) are lower for the subject devices than for the primary predicate and reference device. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. Therefore, the difference would not affect safety and effectiveness of the subject device.	Different. Object devices provide better customization through a wider spectrum of negative pulse width. During the summative evaluation, the users evaluated the feeling of stimulation positively. The main output parameters (output current and output voltage) are lower for the subject devices than for the primary predicate and reference device. This particular feature has already been tested to IEC 60601-1:2005+ A1:2012+ A2:2020. Therefore, the difference would not affect safety and effectiveness of the subject device.
Power source – Battery	Li-ion 4x 3.7V (3.4 Ah)	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.	LiPo 3.7V (2.4Ah)	Similar. Both the predicate and subject devices use rechargeable batteries. For the subject device, a Li-ion battery was selected due to its light weight and compatibility with the compact design.	Similar
Size of the electrodes	Predefined electrode sizes inside the training suit described in User Manual	Predefined electrode sizes inside the training suit described in User Manual	No information publicly available	Similar	N/A

Safety circuits	Overload trip detects short-circuit, No-load trip detects circuit break, battery voltage monitoring, hardware error detection at startup, and watchdog monitoring.	Overload trip detects short-circuit, No-load trip detects circuit break, battery voltage monitoring, hardware error detection at startup, and watchdog monitoring.	Software/Firmware/Micro processor Control: Yes Automatic Overload Trip: Yes Automatic Shut Off: On/Off switch Patient Override Control: Yes, push on On/Off button directly pause the program	Same	Different, subject devices utilize a wider range of safety features
Plugs	The XBody Go USA and XBody Pro USA tablets and the XBody Actiwear G2 wireless stimulation unit are connected wirelessly. The XBody Actiwear G2 and the XBody Training Suit are connected with magnetic connectors. The internal cable of the training suit connects to snap fasteners in the suit to which detachable electrodes are attached via waterproof connections.	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.	No information publicly available	Different. Primary predicate has built-in control panel, while the subject device connects wirelessly with the control unit. The subject devices are worn by the client, therefore no spiral cable is needed to connect with the training suit.	N/A
Lead Wires – Cables	TS2.1: PVC coated ultra-flexible LIFY 0,50 mm2 (256 x 0,05 mm) cables and LiYV 0,56mm2 (7 x	PVC coated ultra-flexible LIFY 0,50 mm2 (256 x 0,05 mm) cables and LiYV 0,56mm2 (7 x 0,32 mm) in the training suit.	No information publicly available	Similar. The subject devices are worn by the client, therefore no spiral cable is needed to connect with the training suit. The wires in the predicate device and TS	N/A

	0,32 mm) in the training suit. Cables are compliant with protected lead wire and patient cable safety requirements TS3.0: Suit cable: Ultra-flexible Microminiature & Miniature PVC Insulated Lead Wire Textile material (yarn): Polyester	Spiral cable with Li12Y11Y25 x 0,14 mm2. Cables are compliant with protected lead wire and patient cable safety requirements		2.1 are the same. The wires in the predicate and the TS 3.0 are similar to eachother.	
Conductivity of the Electrodes	The client must wear an XBody cotton underwear (biocompatibility certified). The electrodes are contained in cotton covers which must be watered using normal tap water to create conductive media. The cotton textiles hold enough water to Provide conductivity during the training. The electrodes are washable and can be disinfected, as described in User Manual.	The client must wear an XBody cotton underwear (biocompatibility certified). The electrodes are contained in cotton covers which must be watered using normal tap water to create conductive media. The cotton textiles hold enough water to provide conductivity during the training. The electrodes are washable and can be disinfected, as described in User Manual.	No information publicly available	Same	N/A
Soldering of the Printed Circuit Boards	In accordance with the ROHS directive, no leadsolder material used.	In accordance with the ROHS directive, no lead solder material used.	No information publicly available	Same	N/A

Placement of the electrodes	The electrodes are located at fixed positions in the training suit ensuring proper placement.	The electrodes are located at fixed positions in the training suit ensuring proper placement.	No information publicly available	Same	N/A
Reusable pads	Yes	Yes	Yes	Same	Same
Number of programs	XBody Go USA: 5 XBody Pro USA: 6	4+10	20	Same to Go USA; Similar to Pro USA	Different XBody devices has a manual program that provides a broader range of stimulation parameters which ensures a more customized training experience compared to the 20 training programs with fixed stimulation parameters of the Wiemspro.
Treatment duration	1 min to 60 min maximum	1 min to 60 min maximum	No information publicly available	Same	The treatment duration is identical to the primary predicate device.
Environment(s) of use	Home healthcare environment, according to IEC 60601-1-11	Home healthcare environment, according to IEC 60601-1-11	No information publicly available	Same	The environment of use is identical to the primary predicate device.
Pulse duration	1-10 s	1-10 s	No information publicly available	Same	The pulse duration is identical to the primary predicate device.
Compliance standards	IEC 60529:1989+ A2:2013+C1:2019 IEC 60601-1:2005+ A1:2012+A2:2020 IEC 60601-1-2:2014 +A1:2020 IEC 60601-1-6:2010 +A1:2013+A2:2020 IEC 60601-1-11:2015 +A1:2020 IEC 60601-2-10:2012 +A1:2016	IEC 60601-1:2005 + C1 + C2 + A1, IEC 60601-1-2:2014, IEC 60601-1-6:2010 + A1:2013, IEC 60601-1-11:2015, IEC 60601-2-10:2012 + A1:2016, IEC 62366:2007 + A1:2014	IEC 60601-1-2:2007 IEC 60601-1-6:2010 IEC 60601-2-10:2012 FCC 47 CFR Part 15 IEC 62304:2006 ISO 14971:2007 ANSI/AAMI ES60601-1:2005 / A2:2010	Since the predicate device is a wired device, wireless Coexistence QoS and Coexistence testing was not required. Due to the subject device's wi-fi capability, it was also tested for additional standards, such as ANSI/AAMI TIR 69:2017, IEEE/ANSI C63.27-2017 and ANSI/AAMI TIR57:2016. The standards are FDA-recognized and align with the Guidance Document "Radio	Due to the subject device's wi-fi capability, it was also tested for additional standards, such as ANSI/AAMI TIR 69:2017, IEEE/ANSI C63.27-2017 and ANSI/AAMI TIR57:2016. The standards are FDA-recognized and align with the Guidance Document "Radio Frequency Wireless Technology in Medical Devices". This ensures the

	IEC 62304:2006 +A1:2015 IEC 62366-1:2015 +A1:2020 ANSI/AAMI TIR 69:2017 IEEE/ANSI C63.27-2017 ANSI/AAMI TIR 57:2016			Frequency Wireless Technology in Medical Devices". This ensures the device's overall safety and effectiveness.	device's overall safety and effectiveness.
Automatic No-Load Trip	YES	YES	YES	Same	Same
Number of Output Modes	One output mode, but with varying stimulation frequency and duty cycle ranges	One output mode, but with varying stimulation frequency and duty cycle ranges	One output mode, but with varying stimulation frequency and duty cycle ranges	Same	Same
Total Dimensions (in.) [W x H x D]	9.65 X 6.9 X 0.33 (tablet) 1.96 X 1.96 X 0.98 (Actiwear G2)	15.74 X 18.11 X 10.63	6.66 X 3.27 X 1.18	Different, subject devices are smaller for a more compact design.	Different, subject devices are smaller for a more compact design.
Housing Materials and Construction	Plastic	Composite	Plastic	Different, subject devices have plastic housing. As a result of its durability, heat resistance, and low maintenance requirements, plastic was chosen as the housing for the subject device.	Same
Footnote: In Table 1, N/A (not available) means that the comparison cannot be made to one of the predicate devices because information is not publicly available.					

Table 2
Comparison of Predicate and Subject Training Suits: XBody Training Suit 2.0, XBody Training Suit 2.1 and XBody Training Suit 3.0

Training suit	Training Suit 2.0 Predicate Training Suit, Cleared for XBody Newave USA (K190038)	Training Suit 2.1 & Training Suit 3.0	Assessment
Compatible product	XBody Newave USA	XBody Go USA XBody Pro USA	Same
Parts	Vest, pants, optional bands	Vest, pants, optional bands	Same
Material	75% Polyamide, 25% Polyester	**TS 2.1**: 75% Polyamide, 25% Polyester (Same as TS 2.0) **TS 3.0**: 40 % Polyamide, 30 % Acrylic, 25 % Polyester, 5 % Elastane	Similar
Underwear required during use	Yes, same underwear for XBody Go USA and Xbody Pro USA. Underwear serves as barrier to direct contact with the body during use.	Yes, same underwear for XBody Newave USA (K190038). Underwear serves as barrier to direct contact with the body during use.	Same
Number of channels	10	12	Similar, but more available channels
Number of electrodes	20 pieces per suit	24 pieces per suit	Similar, but more available electrodes
Weight with electrodes and cables	3 kg (6.6 lbs)	TS2.1: 2.7 – 3.3 kg (6 – 7.3 lbs.) TS3.0: 1.8 - 2.4 kg (4 – 5.3 lbs.)	Similar
Available Sizes	XXS, XS, S, M, L, XL	TS2.1: XXXS, XS, S, M, L, XL, XXL TS3.0: 2, 3, 3-L, 4, 4-L, 5, 5-W, 6, 7, 8	Similar, but wider range of sizes
Available Electrode Sizes and Shapes	5 different electrode shapes	TS2.1: 8 different electrode shapes TS3.0: 10 different electrode shapes	Similar, but wider range of electrode sizes and shapes

The attributes of the Training Suit 2.1, which has “Similar” assessment results are supported by performance testing.

The XBody Training Suit 2.0 is the suit cleared for XBody Newave USA and is similar to XBody Training Suit 2.1 and to XBody Training Suit 3.0 in terms of its intended use. The XBody Training Suit 2.1 and the XBody Training Suit 3.0 material and number of electrodes are similar but not the same as those of the 2.0 version. XBody Training Suit 3.0 includes Acrylic and Elastane to improve comfort during use and a trimmer shape to lessen the total weight. The material of Training Suit 2.1 is the same as of the Training Suit 2.0. In addition, the size of the electrodes for the XBody Training Suit 3.0 are larger and shaped to improve comfort but without affecting performance or safety. The XBody Training Suit 2.1 utilizes the same electrodes as the XBody Training Suit 2.0 but has additional electrode types to improve comfort. The output specifications (i.e., maximum values for output voltage, output current, phase charge, current density, and power density) for the XBody Go USA and XBody Pro USA with either XBody Training Suits are in the approximate

ranges of XBody Newave USA using the XBody Training Suit 2.0 predicate and less than the same electrical parameters for the WiemsPro reference device.

Table 3
Similarities of XBody Go USA and XBody Pro USA and Comparison to Primary Predicate Control Panel Parameters

Parameter	XBody Go USA (Subject Device)	XBody Pro USA (Subject Device)	Comparison of Subject Devices	Subject Devices vs. XBody Newave USA
Control Unit	Microsoft Surface	Microsoft Surface	Same	Similar, built for XB Newave
Dimensions of Control Unit	9.65” x 6.9” x 0.33” (245 mm x 175 mm x 8.3 mm)	11.5” x 7.9” x 0.33” (292 mm x 201 mm x 8.5 mm)	Similar	Different, predicate not a tablet
Wireless Stimulation Unit	XBody Actiwear G2	XBody Actiwear G2	Same	Similar, but predicate not wireless
Training Suit	Able to use XBody Training Suit 2.1 or XBody Training Suit 3.0	Able to use XBody Training Suit 2.1 or XBody Training Suit 3.0	Same	Different, predicate uses TS2.0
Requirement for Underwear	XBody Underwear must be worn during use.	XBody Underwear must be worn during use.	Same	Same
Training Programs	Manual settings, Muscle Development, Endurance, Relax, Professional training programs	Manual settings, Muscle Development, Endurance, Relax, Professional, XBeat training programs	Similar	Similar
Professional Training Features	In person, Virtual trainer, Video editor	In person, Virtual trainer, Video editor	Same	Similar
User Manual	Yes, content varies based on device design	Yes, content varies based on device design	Similar	Similar
Maximum number of Simultaneous Clients	1-2 persons	1-6 persons	Similar	Similar, 1 person for the predicate
Control Panel Storage	Tablet: 64 GB	Tablet: Solid-state drive: 128GB	Similar	Different: Box

Control Panel Display	10.5-inch Tablet Screen	12.3-inch Tablet Screen	Similar	Similar
Control Panel Battery Life	Up to 9 hours of typical device usage	Up to 15 hours of typical device usage	Similar	Different, predicate has Mains Power Source
Control Panel Camera	5.0MP front-facing camera with 1080p Skype HD video; 8.0MP rear-facing autofocus camera with 1080p HD video Dual Studio Mics 2W stereo speakers with Dolby® Audio	5.0MP front-facing camera with 1080p full HD video; 8.0MP rear-facing autofocus camera with 1080p full HD video Dual far-field Studio Mics 1.6W stereo speakers	Similar	Different: No Camera
Wireless type	Wi-Fi: IEEE 802.11a/b/g/n/ac/ax Bluetooth Wireless 5.0 technology	Wi-Fi 6: 802.11ax compatible Bluetooth Wireless 5.0 technology	Similar	N/A
Weight of Control Unit	1.2 lbs. (544 g)	1.70 lbs. (775 g)	Similar	Different, uses a stand

The following is a comparison of the similarities of XBody Go USA/XBody Pro USA and XBody Newave USA as listed in Table 3.

Control unit: XBody Newave USA works with self-made hardware (XBody Newave USA Head) instead of a tablet. In the case of the XBody Go USA and XBody Pro USA systems, the control unit is a Microsoft Surface tablet which is marked as Go 2 or Pro 7+, contains XBody-related software to restrict use only to XBody training, and includes a camera for both units.

Wired and wireless technology: XBody Newave USA works only with a wired configuration, such that the Training Suit 2.0 and the XBody Newave USA head are connected via a spiral cable. In the case of the XBody Go USA and XBody Pro USA systems, there is a new part of the system, the XBody Actiwear G2. XBody Actiwear G2 communicates with the tablets via Wi-Fi.

Camera: XBody Newave USA does not have a camera. The XBody Go USA and XBody Pro USA use the Microsoft Surface cameras.

Number of clients: Using the XBody Newave USA's wired technology, only one client can train at a time. With XBody Go USA only two clients can work out together wirelessly at the same time and with the XBody Pro USA, as many as six clients can train simultaneously.

Software: The subject devices have similar software platforms with some additional programing for the XBody Pro USA compared to XBody Go USA and both predicates, which includes for example the UPBEAT program for audio musical accompaniment to the workout and ability to support group training sessions.

Assessment: Compared to XBody Newave USA, XBody Go USA and XBody Pro USA are 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.

Table 4 **Standard Number and Title Used to Support** **XBody Go USA and XBody Pro USA Safety and Performance**	
Standard Number	**Applied Standards by Title**
ANSI/AAMI 60601-1:2005/(R)2012 and A1:2012.	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010+ A1:2013+A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
IEC 60601-1-11:2015+A1:2020	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systemsused in the home healthcare environment
IEC 60601-2-10:2012+A1:2016	Medical electrical equipment - Part 2-10: Particularrequirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62304:2006+A1:2015	Medical device software - Software life cycle Processes
IEC 60529:1989+A2:2013+ C1:2019	Degrees of Protection Provided by enclosures (IP Code)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.

ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process (Biocompatibility).
ISO 10993-5	Biological evaluation of medical devices - part 5: testsfor in vitro cytotoxicity.
ISO 10993-10	Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization.
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.
EN ISO 13485:2016	Medical Devices – Quality Management Systems –requirements for regulatory purposes
FDA Guidance	Food and Drug Administration Guidance for theContent of Premarket Submissions for Software Contained in Medical Devices 2005
FDA Guidance	Guidance for Industry, FDA Reviewers/Staff and Compliance Guidance Document for Powered MuscleStimulator 510(k)s, June 9, 1999

G. Conclusion of Substantial Equivalence

Electrical safety and electromagnetic compatibility of the XBody Go USA and XBody Pro USA devices are supported by independent testing per international standards, which included the XBody Actiwear G2 unit and XBody Training Suits 2.1 and 3.0.

The subject devices and the primary predicate and reference devices differ in their software programing. The software of the subject devices has been validated to IEC 62304:2006+A1:2015. Based on the independent electrical and electromagnetic compatibility testing and the performance testing of the subject devices, these software differences are directed at fulfilling intended use in a user-friendly interface that does not affect the safety and effectiveness.

Performance testing of the Training Suit 2.1 and the Training Suit 3.0 demonstrated acceptable similarity in intended use to the Training Suit 2.0 that was cleared for the XBody Newave USA Predicate.

Differences in the structures of the control units (i.e., stand-alone fabricated unit vs. modified commercial tablet) between the XBody subject devices and the XBody Newave USA predicate device are mainly due to improvements in design and programming of user interface which are supported by usability performance testing.

The Applied Part is the Underwear required to be worn under the XBody Training Suit 2.0, XBody Training Suit 2.1 and the XBody

Training Suit 3.0. The 2.0 version was cleared under K190038 per ISO biocompatibility standards.

The Power source for the two subject devices is a rechargeable battery that is supported by bench and usability studies and is similar in function and safety to the WiemsPro predicate device. The added feature of the Microsoft Surface camera for the two subject devices is different than that for the two predicates. This has no bearing on device safety and performance.

Conclusion: XBody Go USA and XBody Pro USA are substantially equivalent to their predicate devices. Differences between the subject and predicate devices do not affect safety or performance.

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