May 30, 2025

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

Re: K242926
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: September 20, 2024
Received: September 24, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242926

Device Name

XBody Go USA, XBody Pro USA

Indications for Use *(Describe)*

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 only for 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 their 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.

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]

K242926

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
Submission Contact Person:	Bhoomika Joyappa Senior Regulatory Consultant
Address:	Medical Device Academy, Inc 345 Lincoln Hill Rd, Shrewsbury, VT 05738 bhoomika@fdaestar.com
Date Prepared	5/28/2025

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 Predicate Device

Predicate Device:	XBody Go USA, XBody Pro USA
Manufacturer:	XBody Hungary Kft
Predicate 510(k) Number:	K221200

D. Description of the Devices

The XBody Go USA and the XBody Pro USA generate electronic muscle stimulation based on electrical muscle stimulation (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 predicate devices, the XBody Go USA and XBody Pro USA are the same in indication for use, intended use performance, design, dimensions, and materials as the predicate devices. The new devices meet the same standards for safety and performance as the predicate devices.

The differences cited in the comparison tables between subject and predicate devices do not affect safety and performance of the subject devices when compared for equivalence to the predicate devices.

Parameter / application	**Subject Device XBody Go USA and XBody Pro USA**	**Predicate Device XBody Go USA and XBody Pro USA (K221200)**	**Assessment of substantial equivalence between Subject and Predicate Devices**
510k Number	NA	K221200	NA

Submitter	XBody Hungary Kft	XBody Hungary Kft	Same
Common or Usual Name	Powered muscle stimulator.	Powered muscle stimulator.	Same
Product code	NGX	NGX	Same
Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning	Stimulator, Muscle, Powered, For Muscle Conditioning	Same
Product Classification	Class II	Class II	Same
Review Panel	Physical Medicine	Physical Medicine	Same
Regulated voltage	Yes	Yes	Same
Regulation Name	21 CFR 890.5850	21 CFR 890.5850	Same
Type of use	Prescription Use	Prescription Use	Same
Indications 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 people (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 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 (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.	Same

	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 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 muscle training.	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 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 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 with ease. It is not a mobile device; its intended environment is indoors. Its intended use requires a qualified and trained operator.	Same
User interface	The device can be controlled using the graphical windows appearing on the touchscreen of the external control unit (Microsoft Surface Go 2, Microsoft Surface Go 3 or Microsoft Surface Go 4 for XBody Go USA / Microsoft Surface Pro 7, Microsoft Surface Pro 9 or Microsoft Surface Pro 10 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.	The device can be controlled using the graphical windows appearing on the touchscreen of the external control unit (Microsoft Surface 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.	Similar. Subject devices have more options for control unit devices. The control units are equipped with the same specialized software.

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 stimulation Programs.	Same
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 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.	Same
Display	GO: <10.5" LCD display on the XBody Go USA tablet> PRO: <12.3" or 13" LCD display on the XBody Pro USA tablet >	GO: <10.5" LCD display on the XBody Go USA tablet> PRO: <12.3" LCD display on the XBody Pro USA tablet >	Similar. The XBody Pro USA subject device has optional control units equipped with slightly bigger displays.
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).	Same
Output specifications	Max Output Voltage = 20.8V @500Ω	Max Output Voltage = 20.8V @500Ω	Same
	Max Output Current = 41.6mA @500Ω	Max Output Current = 41.6mA @500Ω	Same
	Max Phase Charge = 16.64µC@500Ω	Max Phase Charge = 16.64µC@500Ω	Same
	Max Current Density =0.65mA/cm2 @500Ω	Max Current Density =0.65mA/cm2 @500Ω	Same
	Max Power Density =3.46mW/cm2 @500Ω	Max Power Density =3.46mW/cm2 @500Ω	Same
Net Charge (µC per pulse)	0 @500Ω (each phase uses symmetric waveform)	0 @500Ω (each phase uses symmetric waveform)	Same
Shape	Rectangular	Rectangular	Same

Number of Output channels	6 output channels, but maximum 12 independently regulated outputs in case of Training Suit (TS) 2.1 and TS 3.0. 5 output channels, but maximum 10 independently regulated outputs in case of DrySuit	6 output channels, but 12 independently regulated outputs	Similar The subject devices have the option to use the DrySuit which has only 10 channels.
Waveform	Symmetric biphasic	Symmetric biphasic	Same
Burst mode - Pulses per burst	100 * 10 = 1000	100 * 10 = 1000	Same
Burst mode - Bursts per second	0.1	0.1	Same
Burst mode - Burst duration (seconds)	11	11	Same
Burst mode - ON Time (seconds)	10	10	Same
Burst mode - OFF Time (seconds)	1	1	Same
Burst mode - Duty Cycle: Line (d)/(Line (d)+ Line (e))*	0.91	0.91	Same
Additional Features (specify, if applicable)	N/A	N/A	Same
Output frequency	1-150Hz	1-150Hz	Same
Positive pulse width	50-500usec	50-500usec	Same
Negative pulse width	50-500usec	50-500usec	Same
Power source – Battery	Li-ion 4x 3.7V (3.4 Ah)	Li-ion 4x 3.7V (3.4 Ah)	Same

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	Same
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.	Same
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.	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.	Same
Lead Wires – Cables	TS2.1: PVC coated ultra-flexible LIFY 0,50 mm2 (256 x 0,05 mm) cables and LiYV 0,56 mm2 (7 x 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 DS: PFA coated stainless steel filaments cored yarn (1.0mm~1.05mm) 275F*6, 316L	TS2.1: PVC coated ultra-flexible LIFY 0,50 mm2 (256 x 0,05 mm) cables and LiYV 0,56 mm2 (7 x 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	Similar The subject devices have the option to use the DrySuit with its own lead wire

Conductivity of the Electrodes	When using the TS 2.1 or TS 3.0, the client has two options: wearing an XBody cotton underwear (biocompatibility certified), or wearing the DryWear with lightweight thin undergarments that do not obstruct the connection between the electrodes and the skin on the glutes. When using the cotton underwear, 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. When using the XBody DryWear with undergarments, the electrodes of the TS2.1 or TS3.0 are fixed in the training suit with Velcro attachments, instead of cotton covers. Conductive media in this case is the DryWear. The XBody DrySuit must be worn with lightweight thin undergarments that do not obstruct the connection between the electrodes and the skin on the glutes. The XBody DrySuit transmits electrical stimulation to the surface of the skin without the use of water.	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.	Similar
Soldering of the Printed Circuit Boards	In accordance with the ROHS directive, no lead solder material used.	In accordance with the ROHS directive, no lead solder material used.	Same
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.	Same
Reusable pads	Yes	Yes	Same
Number of programs	XBody Go USA: 5 XBody Pro USA: 6	XBody Go USA: 5 XBody Pro USA: 6	Same
Treatment duration	1 min to 60 min maximum	1 min to 60 min maximum	Same
Environment(s) of use	Home healthcare environment, according to IEC 60601-1-11	Home healthcare environment, according to IEC 60601-1-11	Same
Pulse duration	1-10 s	1-10 s	Same

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 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	Same

	IEC 60601-1-11:2015 +A1:2020 IEC 60601-2-10:2012 +A1:2016 IEC 62304:2006 +A1:2015 IEC 62366-1:2015 +A1:2020	IEC 60601-1-11:2015 +A1:2020 IEC 60601-2-10:2012 +A1:2016 IEC 62304:2006 +A1:2015 IEC 62366-1:2015 +A1:2020	
Compliance with 21 CFR 898?	YES	YES	Same
Automatic No-Load Trip	YES	YES	Same
Method of Line Current Isolation	N/A (battery-operated device)	N/A (battery-operated device)	Same
Patient leakage current – normal condition (µA)	N/A (battery-operated device)	N/A (battery-operated device)	Same
Patient leakage current – single fault condition (µA)	N/A (battery-operated device)	N/A (battery-operated device)	Same
Synchronous or alternating?	N/A (battery-operated device)	N/A (battery-operated device)	Same
Method of Channel Isolation	Hardware and timing	Hardware and timing	Same
Regulated Current or Regulated Voltage?	Regulated current and voltage	Regulated current and voltage	Same
Software/Firmware/ Microprocessor Control?	Yes	Yes	Same
Automatic Over current Trip? Yes/no	Yes	Yes	Same
Patient Override Control? Yes/no	Yes	Yes	Same
Patient Override Control method	Disconnect suit connectors	Disconnect suit connectors	Same
Indicator Display	Yes	Yes	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	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)	9.65 X 6.9 X 0.33 (tablet) 1.96 X 1.96 X 0.98 (Actiwear G2)	Same
Housing Materials and Construction	Plastic	Plastic	Same

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

Training suits	XBody Training Suit 2.1 & Training Suit 3.0 Predicate training suits for XBody Go USA and XBody Pro USA (K221200)	XBody DrySuit	Assessment
Compatible product	XBody Go USA XBody Pro USA	XBody Go USA XBody Pro USA	Same
Parts	Vest, pants, optional bands	Jacket, pants	Same
Material	**TS 2.1**: 75% Polyamide, 25% Polyester (Same as TS 2.0) **TS 3.0**: 40 % Polyamide, 30 % Acrylic, 25 % Polyester, 5 % Elastane	75% Polyester, 15% Spandex, 15% Elastane	Similar
Underwear required during use	Yes. Option 1: same underwear for XBody Newave USA (K190038). Underwear serves as barrier to direct contact with the body during use Option 2: XBody DryWear worn over lightweight thin undergarments that do not obstruct the connection between the electrodes and the skin on the glutes. XBody DryWear is new to this submission.	Yes. The XBody DrySuit must be worn over lightweight thin undergarments that do not obstruct the connection between the electrodes and the skin on the glutes. The XBody DrySuit contacts the skin of the client directly.	Different
Number of channels	12	10	Similar, but less available channels
Number of electrodes	24 pieces per suit	20 pieces per suit	Similar, but less available electrodes
Weight with electrodes and cables	TS2.1: 2.7 – 3.3 kg (6 – 7.3 lbs.) TS3.0: 1.8 - 2.4 kg (4 – 5.3 lbs.)	1 kg (2.2 lbs.)	Similar
Available Sizes	TS2.1: XXXS, XS, S, M, L, XL, XXL TS3.0: 2, 3, 3-L, 4, 4-L, 5, 5-W, 6, 7, 8	XXS/2, XS/3, S/4, M/5, L/6, XL/7, XXL/8, XXXL/9	Similar

Available Electrode Sizes and Shapes	TS2.1: 8 different electrode shapes TS3.0: 10 different electrode shapes	9 different electrodes	Similar

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

Parameter	XBody Go USA (Subject Device)	XBody Pro USA (Subject Device)	Comparison of Subject Devices	Subject Devices vs. Predicate Devices
Control Unit	Microsoft Surface	Microsoft Surface	Same	Same
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	Same
Wireless Stimulation Unit	XBody Actiwear G2	XBody Actiwear G2	Same	Same
Training Suit	Able to use XBody Training Suit 2.1, XBody Training Suit 3.0 and XBody DrySuit	Able to use XBody Training Suit 2.1, XBody Training Suit 3.0 and XBody DrySuit	Same	Similar. Predicate can only use XBody Training Suit 2.1 and XBody Training Suit 3.0
Requirement for Underwear	XBody Cotton underwear or XBody DryWear worn over undergarments must be worn during use with XBody Training Suit 2.1 and XBody Training Suit 3.0. Undergarments must be worn with the XBody DrySuit.	XBody Cotton underwear or XBody DryWear worn over undergarments must be worn during use with XBody Training Suit 2.1 and XBody Training Suit 3.0. Undergarments must be worn with the XBody DrySuit.	Same	Similar. Predicate can only use XBody Training Suit 2.1 and XBody Training Suit 3.0
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	Same
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
Control Unit Storage	Tablet: 64 GB	Tablet: Solid-state drive: 128GB	Similar	Similar
Control Unit Display	10.5-inch Tablet Screen	12.3-inch Tablet Screen	Similar	Similar

Control Unit Battery Life	Up to 9 hours of typical device usage	Up to 15 hours of typical device usage	Similar	Similar

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	Similar
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	Similar
Weight of Control Unit	1.2 lbs. (544 g)	1.70 lbs. (775 g)	Similar	Similar

The following is a comparison of the similarities of the subject and predicate devices as listed in Table 3.

Control unit: For the predicate devices, the control devices were limited to the Microsoft Surface Go 2 for the XBody Go USA and the Microsoft Surface Pro 7 for the XBody Pro USA. For the subject devices, the available control devices include the Microsoft Surface Go 2, Microsoft Surface Go 3, and Microsoft Surface Go 4 for the XBody Go USA, and the Microsoft Surface Pro 7, Microsoft Surface Pro 9, and Microsoft Surface Pro 10 for the XBody Pro USA. This change does not impact safety or performance, as the newly introduced control units operate the same software developed by XBody Hungary Kft., have similar specifications, and exhibit identical performance.

Number of clients: Using the predicate or the subject device versions of the XBody Go USA, the same number of clients can train at a time. Using the predicate or the subject device versions of the XBody Pro USA, the same number of clients can train at a time.

Assessment: The subject devices and the predicate devices are the same in terms of intended use, performance, and design. Similarities derive from the introduction of the XBody DrySuit and DryWear. The new device meets the same standards for safety as the predicate device.

Specification	Microsoft Surface Go 2	Microsoft Surface Go 3	Microsoft Surface Go 4
Execution platform	Intel® Pentium® Gold Processor 4425Y 8th Gen	Intel® Pentium® Gold Processor 6500Y 10th Gen	Intel N200
CPU Cores	2	2	4
RAM	4 GB	4 GB	8 GB
Graphics	Intel® UHD Graphics 615	Intel® UHD Graphics 615	Intel UHD Graphics
Display	10.5”, 1920 x 1280, 10-point multi-touch	10.5”, 1920 x 1280, 10-point multi-touch	10.5”, 1920 x 1280, 10-point multi-touch
Storage	eMMC drive: 64GB	eMMC drive: 64GB	UFS Drive: 64GB, 128GB, 256GB
Connections	1 USB Type-C, HDMI over	1 USB Type-C, HDMI over	1 USB Type-C, HDMI over

	docking adapter or Type-C	docking adapter or Type-C	docking adapter or Type-C
Wireless communication	Wi-Fi 6, BT/BLE 5	Wi-Fi 6, BT/BLE 5	Wi-Fi 6, BT/BLE 5.1
Security	TPM 2.0, UEFI secure boot	TPM 2.0, UEFI secure boot	TPM 2.0, UEFI secure boot
OS support	Linux kernel supported	Linux kernel supported	Linux kernel supported
Construction	Handheld tablet with integrated battery	Handheld tablet with integrated battery	Handheld tablet with integrated battery

Specification	**Microsoft Surface Pro 7**	**Microsoft Surface Pro 9**	**Microsoft Surface Pro 10**
Execution platform	Intel® i5-1035G4 10th Gen	Intel® i5-1245U 12th Gen	Intel Core Ultra 5 Processor 135U Intel Core Ultra 7 Processor 165U
CPU Cores	4	4	12
RAM	8 GB	8 GB	8GB, 16GB, 32GB, 64GB
Graphics	Intel® Iris Plus Graphics 615	Intel® Iris XE Graphics 615	Intel Graphics
Display	12.3”, 2736 x 1824, 10-point multi-touch	13.0”, 2880 x 1920, 10-point multi-touch	13.0”, 2880 x 1920, 10-point multi-touch
Storage	SSD drive: 128GB	SSD drive: 256GB	SSD drive: 256GB, 512GB, 1TB
Connections	1 USB Type-C, HDMI over docking adapter or Type-C	1 USB Type-C, HDMI over docking adapter or Type-C	2 USB Type-C, HDMI over docking adapter or Type-C
Wireless communication	Wi-Fi 6, BT/BLE 5	Wi-Fi 6E, BT/BLE 5.1	Wi-Fi 6E, BT/BLE 5.3
Security	TPM 2.0, UEFI secure boot	TPM 2.0, UEFI secure boot	TPM 2.0, UEFI secure boot
OS support	Linux kernel supported	Linux kernel supported	Linux kernel supported
Construction	Handheld tablet with integrated battery	Handheld tablet with integrated battery	Handheld tablet with integrated battery

Table 6
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 have been validated through independent testing in accordance with international standards. This testing covered the XBody Actiwear G2 main unit, the control unit, the XBody Training Suit 2.1, the XBody Training Suit 3.0 (all four used in both the subject and predicate devices), and the XBody DrySuit, which is newly included in this submission.

The subject devices and the predicate devices have the same software programming except for minor functionalities. The software of the subject devices has been updated to include a feature that allows users to select the DrySuit among the available training suits. Independent electrical and electromagnetic compatibility testing, along with performance testing of the subject devices, confirms that these software differences are aimed at enhancing the user interface without impacting safety and effectiveness.

Performance testing of the XBody DrySuit demonstrated acceptable similarity in intended use to the XBody Training Suit 2.1 and the XBody Training Suit 3.0, both of which were previously cleared for the XBody Go USA and XBody Pro USA predicate devices.

The predicate devices' sole applied part is the cotton underwear, which was required to be worn under the XBody Training Suit 2.1 and the XBody Training Suit 3.0. The subject devices have optional applied parts, cotton underwear (same as the predicates') and the XBody DryWear, both of which can be interchangeably worn under the XBody Training Suit 2.1 and the XBody Training Suit 3.0. Additionally, the newly introduced applied parts, the XBody DrySuit and DryWear must be worn with undergarments that do not obstruct the connection between the electrodes and the skin on the glutes..

The Power source of the subject and predicate devices is the same rechargeable battery, supported by bench and usability studies.

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

END OF DOCUMENT.