June 7, 2019

miha bodytec GmbH
% Rhonda Alexander
Sr. Consultant, Leadership & Regulatory Development
IUVO Consulting, LLC
P.O. Box 56483
Virginia Beach, Virginia 23456

Re: K182519
Trade/Device Name: miha bodytec II
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 3, 2019
Received: May 6, 2019

Dear Rhonda Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Vivek Pinto
Assistant Director, Acute Injury 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182519

Device Name
miha bodytec II

Indications for Use *(Describe)*
miha bodytec II 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 healthy muscles and clients, not be used for rehabilitation purposes.

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

The miha bodytec II 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 miha bodytec II can impose on the stimulated muscles are able to improve or facilitate muscle performance. The miha bodytec II 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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510(k) Summary

for

miha bodytec II

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

1 Sponsor

Sponsor: miha bodytec GmbH
Siemensstr. 1
86368 Gersthofen
Germany

Contact Person: Dr. Rhonda Alexander
IUVO Consulting, LLC
(757) 582 – 4337
ralexander@iuvoconsulting.com

Date Prepared: May 2, 2019

2 Device Name and Classification

Proprietary Name: miha bodytec II

Common/Usual Name: Powered muscle stimulator

Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning
(21 CFR 890.5850, Product Code NGX)

3 Predicate Device

Predicate Device: E-Fit EF-1280, K133225

4 Intended Use

miha bodytec II 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 healthy muscles and clients, not be used for rehabilitation purposes.

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

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

5 Device Description and Function

miha bodytec II is a transcutaneous electrical muscle stimulation (EMS) device which stimulates motor nerves by means of electrical impulses transmitted by electrodes. These excitations of motor nerves are transmitted to the muscle fibers where they stimulate a muscular response. Depending on the parameters of the electrical impulses (pulse frequency, pulse intensity, pulse duration, pulse width, pulse rise, pause time, total session duration), different types of muscle work can be imposed on the stimulated muscles.

miha Bodytec II consists of a control unit mounted on a stand for the selection of programs, setting the parameters and starting/stopping the device, the i-body® electrode vest for applying electrodes to the upper body, i-body® straps for applying electrodes to the arm and legs and the i-body® belt for applying electrodes to the buttocks. The control unit and the i-body® accessories are connected via cables and must be worn on top of optionally available undergarment.

miha bodytec II must be used in a professional sport setting. The device must be operated by a trainer who has received a full training from the manufacturer. Before the training, the trainer selects the accessories incl. electrodes in the correct size, applies the electrodes to the athlete i.e. by wearing the electrode vest and connects the straps und belt via cable to the vest and to the control unit. The trainer can choose between several training programs on the control unit for impulse familiarization, invigoration basic/advanced, muscular endurance and body relax. The intensity can be adjusted by the trainer at the UI of the control unit separately for each channel. Complete body training which addresses all muscle groups is possible with up to 10 pairs of electrodes. Each athlete receives an RFID transponder card for storing training results and individually adjusted programs. Once the training is started, the control unit generates and transmits the electrical signals to the electrodes via cable. miha bodytec II uses bipolar pulses and supplies all channels equally during all programs.

During pulse application, the trainer instructs the athlete on specific exercises to perform. The training can be stopped anytime by pressing the multi-function / stop button.

6 Predicate Device Comparison

6.1 General

Characteristic	New Device	Predicate Device	Similar / Different
510(k) Number	K182519	K133225	-
Device Name, Model	miha bodytec II	E-Fit EF-1280	-
Manufacturer	miha bodytec GmbH	Fit-Pro KFT Ltd.	-
Indications for Use	miha bodytec II 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 healthy muscles and clients, not be used for rehabilitation purposes. miha bodytec II is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. miha bodytec II is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the miha bodytec II training programs are designed for injured or ailing muscles and its use on such muscles is contraindicated.	E-fit EF-1280 is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes. The E-Fit EF-1280 intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit EF-1280 is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the E-Fit EF-1280 training programs is designed for injured or ailing muscles and its use	There are no differences between the subject device and the predicate(s) with respect to indications and intended use.

	The miha bodytec II 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 miha bodytec II can impose on the stimulated muscles are able to improve or facilitate muscle performance. The miha bodytec II may therefore be considered a technique of muscle training.	on such muscles is contraindicated. The E-Fit EF-1280 electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the E-Fit EF-1280 can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit EF-1280 may therefore be considered a technique of muscle training.	

Connection of the device to electrodes	One stimulation module / control unit which is channel-wise connected to the i-body® electrodes over a cable to the i-body® vest. The electrodes of the i-body® straps and belt are connected via cables to the vest.	One stimulation module / main unit which is channel-wise connected to the EF-jacket and EF-shorts.	Similar electrode connection from a control unit to the electrodes
Power Source(s)	Control unit: 15 V – 19 V; External power supply (100 – 240 V ~ 50 – 60 Hz)	12V (3,4Ah) lead Acid battery	Different. The external power supply of subject device was tested according to AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012. No new concerns regarding safety and effectiveness were raised during verification and validation.
- Method of Line Current Isolation	Power Supply in accordance with IEC 60601-1	N/A (battery operated device)	Different. See comment on power source.
- Patient Leakage Current	< 100 µA	N/A (battery operated device)	Different. See comment on power source.
- Normal condition	< 100 µA	N/A (battery operated device)	Different. See comment on power source.
- Single fault condition	< 100 µA		Different. See comment on power source.
Number of Output Modes	One (symmetric biphasic) with 6 training programs	One (symmetric biphasic)	Similar. Both devices provide one output symmetric biphasic output mode.
Number of Output Channels	10, channel selective stimulation**.** Maximum one channel is active at any time.	10+2. The output channel can shift in time to the 12 outputs but electrical current can be regulated individually on every output	Similar, both devices use multiplexing and alternating activation of the output channels.

- Synchronous or Alternating	Alternating	Alternating	Similar, see comment above.
- Method of Channel Isolation	Multiplexed by control unit	Multiplexed by control unit	Similar, see comment above.
Regulated Current or Regulated Voltage	Regulated voltage (all channels)	Regulated current (all channels)	Different regulation mechanism. However, both are safe and effective and comply with IEC 60601-2-10.
Software/ Firmware/ Microprocessor Control	Yes	Yes	Similar. Both devices are firmware-driven.
Automatic Overload Trip	Yes, no load and short circuit conditions are handled	Yes	Similar. Both devices no-load and overload condition handling.
Automatic No-Load Trip	Yes, no load and short circuit conditions are handled	Yes	Similar. Both devices no-load and overload condition handling.
Automatic Shut Off	On/Off-Switch, stimulation stops after defined duration, automatic stop of stimulation in case of failure / malfunction detected	On/Off-Switch, Watchdog monitoring, hardware error monitoring, output current monitoring (emergency stop option)	Similar. Both devices provide a hardware on/off-switch as well as error monitoring implemented in the firmware.
Patient Override Control	Yes, while a program is active the patient is supervised by a trainer and able to manipulate intensity (amplitude) and push the stop button	Yes, while a program is active the patient is supervised by a trainer and able to manipulate intensity (amplitude) and push the pause button	Similar, both devices require the operation by a qualified trainer.
Indicator Display:	Yes	Yes	Similar, both devices provide a display.

- On/Off Status	Yes	Yes	Similar, both devices show the on/off status.
- Low Battery	N/A, no battery	Yes	Different. Not applicable to miha bodytec II since no battery is used.
- Voltage/ Current Level	Yes, displayed in form of percentage / value range	Yes, displayed in form of percentage / value range	Similar, both devices display the voltage / current level.
Timer Range / Program Duration (minutes)	Training should not exceed 20 minutes; Screen shows remaining time in minutes and displays image showing time remaining	Maximum = 30 minutes	Similar, both manufacturers recommend a similar maximum training duration.
Number of Programs	11	5+5	Similar number of programs / training plans.
User Interface	Physical buttons and rotary knobs with pictographs of the trained muscles for a quick und usability-oriented setting of the intensity values and multi-functional button for setting, program selection and START/STOP for immediate stimulation stop, power-off button, RFID transponder card placement area. 10.1 inch non-touch LC color display for program / training plan selection via menu, settings, device status, training mode display (animated avatar, timer, selected program)	The rotary encoder allows for a quick set-up and because of the push button capability, the program can be stopped immediately for every channel. There are large START/STOP and POWER off buttons to begin the program and for complete power shutdown. Because of the pictographs and fixed electrodes in the clothing, it is very easy to set the appropriate muscle groups. Simple one-level menu system. LC 2x40 character LCD display with LED backlight.	Similar. However, miha bodytec II provides a larger display for changing settings, choosing programs / training plans, and providing relevant information during training. The UI of miha bodytec was tested for usability according to FDA's guidance.
Portability / Mobile Use	Portable with difficulty, no mobile device, its intended	Portable with difficulty, no mobile	Similar, both devices are portable with difficulty.

<table>
<tr><td></td><td>use requires the qualified and trained operator.</td><td>device, its intended use requires the qualified and trained operator.</td><td></td></tr>
<tr><td>Operator</td><td>The device must only be operated by a trainer, who received full training by miha bodytec.</td><td>By manufacturer recommendations, the only person who can operate the device must obtain certifications by the seller. This person must complete the certification prior to use on a patient.</td><td>Similar. Both devices require operation by a qualified trainer who received a manufacturer training.</td></tr>
<tr><td>Compliance with 21 CFR 898

(Mandatory since May 9, 2000)</td><td>Yes</td><td>Yes</td><td>Similar</td></tr>
<tr><td>Size of electrodes</td><td>Electrodes with pre-defined size of 9.75 – 64.36 in², supplied with the device.

Length x Width of electrode pads:
3,42 - 30,94 in x 3,15 - 4,37 in

<table><tr><td>Vest size</td><td>Size 1 and size V1 in in²</td><td>Size 2, size 3 and size v2 in in²</td></tr><tr><td>2 electrodes for abdomen</td><td>22.85</td><td>27.56</td></tr><tr><td>2 electrodes for chest</td><td>10.31</td><td>12.81</td></tr><tr><td>2 electrodes for upper back</td><td>16.25</td><td>20.98</td></tr></table></td><td>Electrodes with pre-defined (supplied with the device) size and correct position from 12.40 in² to 58.13 in².
Length x Width of electrode pads:
3,94 – 9,84 in x 3,94 – 6,30 in</td><td>Similar size of electrodes.</td></tr>
</table>

	2 electrodes for sides of back: 9.75 / 11.85 2 electrodes for lower back: 14.4 / 19.47 Strap size / Electrode size in² Size 1 (pair): Each 34.15 Size 2 (pair): Each 48.77 Size 3 (pair): Each 64.36 Strap size / Electrode size in² Size 1 (pair): Each 14.7 Size 2 (pair): Each 18.34		
Plugs	Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Cables between vest and strap / belt with proprietary connectors.	Cables connect to the electrodes with snap fastener and connect to the machine with plastic 12pin waterproof ip68 connector.	Different plug design. However both devices have been successfully tested according to the relevant recognized safety standards (IEC 60601).
Lead wires - cables	1. Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Length: 3000 mm, Polyurethane jacket. 2.1-pole-cables between vest and strap / belt: 15,75 in, 19,29 in, 30,71 in, PVC jacket. 3. Cables within vest: firmly mounted into the vest; Polyurethane jacket	SIFF 1-1.5mm² (1x375 unique filaments) ultra flexible – Compliant with protected lead wire and patient cable safety requirements	Similar. Both devices have been successfully tested according to the relevant recognized safety standards (IEC 60601).

	Compliant with protected lead wire and patient cable safety requirements		
Placement of the electrodes	Appropriately pre-placed in specific areas according to muscle anatomy. Electrodes are firmly mounted into the vest, belt or straps. The electrodes itself cannot be separated from the textile and cannot be exchanged.	Appropriately preplaced in specific areas according to muscle anatomy. Electrodes are only fixed by velcro and can be exchanged.	Similar areas of electrode Placement. Different possibility to exchange the electrodes. However, with the miha bodytec II there is no risk of incorrect electrodes being used by mistake.
Material of electrodes	The conductive electrode itself (under the textile) is made out of a 100% BEKINOX Stainless Steel multifilament yarn. No direct skin contact possible.	No direct skin contact. Further information not publicly available.	N/A
Maximum duration for use per treatment	Max. 20 minutes per treatment.	Max. program duration 30 minutes.	Similar
Conductivity of the electrodes	The athlete needs to put on the genuine and biocompatible miha bodytec undergarments (pants and shirt) under the i-body accessories (vest, strap and belt). The absorbent electrodes cover on the i-body vest, strap and belt need to be moistened using a pump spray bottle with tap water. The electrode vest, straps and belt are washable.	The subject needs to put on an 100% hygroscopic cotton underwear (surgery textile, biocompatibility certified) and these underwear needs to be soaked / irrigated with normal tap water. So the electro conductive media is simply tap watered cotton which is in contact with the electrodes. The surface of the electrode will not get dry. In this case the pulse transmission efficiency will not decrease. The small conductive pads are	Different. However, both approaches are effective, the difference of miha bodytec II is that the undergarments do not need to be completely soaked with water.

		washable and disinfectable.	
Accessories	i-body vest i-body strap i-body belt Undergarments Transponder card	EF-Jacket EF-Shorts EF arm and should straps Undergarments	Similar types of accessories.
Weight	Complete: 45.2 lb Control unit: 10.3 lb i-body® with cable set: 3.3 lb i-body® belt: 0.9 lb i-body® strap: 0.55 lb	Complete: 53.57 lb	Similar in weight.
Dimensions (ft.) [W x H x D]	Control unit: 1.39 × 0.89 × 0.23 (W × D × H in ft) Complete: 1.77 × 1.69 × 3.89 (W × D × H in ft)	Control unit: 1.43 x 0.26 x 0.85 (W × D × H in ft)	Similar in dimensions.
Housing Materials and Construction	**Control unit:** Aluminum	**Enclosure:** Stainless steel	Different housing material. However, both devices have been successfully tested according to the relevant recognized safety standards (IEC 60601).
Standards	ISO 14971:2007 AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2010 IEC 60601-2-10:2012 IEC 62304:2015 IEC 62366-1:2015 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	ISO 14971:2012 EN ISO 13485:2003 /AC2009 IEC 60601-1:2005 3rd edition IEC 60601-1-2:2007 IEC 60601-1-11:2010 IEC 60601-2-10:2012	Similar, several additional standards applied by miha bodytec

Table 1: Basic Device Characteristics – Comparison with Predicate Device

6.2 Output Specifications

Characteristic	New Device	Predicate Device	Similar / Different
Waveform	Symmetric biphasic	Symmetric biphasic	Similar output.

Shape	Rectangular	Rectangular	Similar shape.
Maximum Output Voltage	<= 74Vp @ 500Ω (54 - 74 Vp) <= 152Vp @ 2kΩ (110 … 152 Vp) <= 152Vp @ 10kΩ (130 … 152 Vp)	36V @500Ω	Different maximum output values. However, this does not raise new questions regarding safety and effectiveness since both devices comply and are within the limits of IEC 60601-2-10.
Maximum Output Current	< 148mAp @ 500Ω (108-148mAp) < 76mAp @ 2kΩ (55-76mAp) < 15 mAp @ 10kΩ (13-15mAp)	72mA @500Ω	Different maximum output current. However, this does not raise new questions regarding safety and effectiveness since both devices comply and are within the limits of IEC 60601-2-10.
Pulse Width	50 - 400 µs	100 - 500 µs	Similar pulse width.
Frequency (Hz)	2 - 150 Hz	5 - 120 Hz	Similar frequency.
Symmetrical phases	Yes	Yes	Similar
Phase Duration	25 … 200 µs	50 … 250 µs	Similar phase duration.
Maximum Phase Charge	<32 µC @ 500Ω	36 µC @ 500Ω	Similar maximum phase charge
Maximum Current Density	0.64 mA/cm² @ 500Ω	0.85 mA/cm² @ 500Ω	Similar maximum current density
Maximum Power Density	0.82 mW/cm² @ 500Ω	6.3 mW/cm² @ 500Ω	Different maximum power density. However, both devices fulfill the requirements of IEC 60601-2-10.
Burst Mode	Contraction time: 1 – 10 s Relaxation time: 0.0 – 10 s	Contraction time: 0.1 – 30 s Relaxation time: not specified	Similar burst mode

Safety circuits	Short-circuit monitoring, watchdog monitoring, no load trip, onload trip, button for immediate shut off, redundant hardware error monitoring (emergency STOP option) Firmware self-tests.	Short-circuit monitoring, watchdog monitoring, no load trip, onload trip, battery monitoring, battery voltage monitoring, output current monitoring (emergency STOP option), option for self-test, hardware error monitoring.	Similar safety features provided.

Table 2: Output Specifications – Comparison with Predicate Device

6.3 Summary of technological characteristics:

Miha bodytec II and the predicate device have the same indications for use and similar technological characteristics and features. Both use wired connections between the control unit to the electrodes, specifically designed biocompatible undergarment, electrode connector accessories which are placed on the undergarment and not directly on the skin and slightly different output specifications, cable specifications, however, both within the limits given by IEC 60601-2-10. miha bodytec II is powered by line voltage, whereas the E-Fit 1280 is battery-driven. The power supply is located outside the control unit and was tested according to IEC 60601-1. No additional concerns regarding safety and effectiveness were raised.

None of these differences raise any new issues regarding safety or effectiveness.

7 Performance Testing

Electrical Safety and Electromagnetic Compatibility testing: miha bodytec II was tested according to and is in compliance with recognized standards for electrical safety and electromagnetic compatibility.

Software and System validation: The miha bodytec II comprises firmware which was verified and validated according to IEC 62304 and FDA’s guidance: General Principles of Software Validation. Software validation demonstrated that the firmware met the software system requirements. The full system validation testing also included testing in accordance with the recommendations of FDA's “Guidance Document for Powered Muscle Stimulator 510(k)s” issued on June 9, 1999. Oscilloscope tracings were obtained of the device output waveforms under maximum supported voltage and pulse widths under loads of 500 Ω, 2 kΩ and 10 kΩ. Additional System-level tests were conducted, including electrical tests of the interfaces, thermographic inspections, tests in climate chamber, shock and vibration tests.

Usability validation: The overall system was validated to confirm that the device meets its intended use, i.e. can be used safe and effectively by the specified users within the specified use environment, taking into account human factors and usability requirements.

Biocompatibility testing: Skin contacting material was tested to ISO 10993-5:2009 and ISO 10993-10:2009.

Shelf life and dispersion testing:

Bench testing of the electrodes was performed to demonstrate uniform current distributions (dispersion testing). The test case was built up according to FDA's requirements.
4 batches of electrodes were tested. From each batch 8 chest-electrodes (yellow), 8 lateral back-electrodes (blue), 1 upper back-electrode (green) and 1 abdomen-electrode (red) were selected (see Annex III). The electrodes were cut out of the vest and moistened to be covered by the undergarments. 8 measure points from each chest-electrode (yellow), each lateral back-electrode (blue) and each upper back-electrode (green) as well as 5 measure points from each abdomen-electrode (red) were defined. As indicated by FDA the electrodes were measured prior to and after cleansing. After this measuring period the accelerated aging was applied and followed by another measuring period which was conducted exactly the same like the first one. All tests successfully passed.

To calculate the shelf life, we establish new testing according to ASTM F 1980-16. In a climate cabinet an accelerating aging condition for the electrodes was simulated at 60°C for 4 weeks. Through conducting a typical training current while being in the climate cabinet, a 1 year shelf life as well as a 1 year storage was tested. Altogether 72 electrodes were tested. All tests successfully passed.

8 Performance Standards

miha bodytec II complies with the applicable requirements of the following international and

national standards:

- IEC 60601-2-10:2012 - Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators
- IEC 60601-1-2:2014 - Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-11:2010 - 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
- IEC 62304:2015 - Medical Device Software - Software Life Cycle Processes

- ISO 14971:2007 - Medical Devices - Application Of Risk Management To Medical Devices
- IEC 62366-1:2015 - Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
- ISO 10993-1:2009 - Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- ISO 10993-5:2009 - Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

The following FDA Guidance Documents have been applied:

- Guidance Document for Powered Muscle Stimulator 510(k)s, Document issued on: June 9, 1999
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005
- General Principles of Software Validation issued on: January 11, 2002
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Document issued on: June 14, 2013
- Cyber security for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on: January 14, 2005
- Off-the-Shelf Software Use in Medical Devices, Document issued on: September 9, 1999

9 Conclusion

Based on the comparison of the intended use, technological characteristics and performance testing, miha bodytec believes that the miha bodytec II system is substantially equivalent to the predicate device E-Fit EF-1280.