March 11, 2021

miha bodytec GmbH
Felix Schweigert
QA/RA Manager
Siemensstr. 1
Gersthofen, 86368
Germany

Re: K201975
Trade/Device Name: miha bodytec II
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, IPF
Dated: December 9, 2020
Received: December 14, 2020

Dear Felix Schweigert:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201975

Device Name
miha bodytec II

Indications for Use *(Describe)*
miha bodytec II (MBT 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.

miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions:

- Re-educating muscles
- Relaxation of muscle spasm
- Retarding or preventing disuse muscle atrophy

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.

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.

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

Sponsor

Sponsor: miha bodytec GmbH
Siemensstr. 1
86368 Gersthofen
Germany

Contact Person: Felix Schweigert
fs@miha-bodytec.de
Germany: +49 821 45 54 92 - 22
US: +1 833 367 6442

Date Prepared: July 06, 2020

510(k) number: K201975

Device Name and Classification

Proprietary Name: miha bodytec II

Common/Usual Name: Powered muscle stimulator

Classification Name: Stimulator, Muscle, Powered
(21 CFR 890.5850, Product Code NGX and IPF)

Predicate Device

Predicate Device: Primary: miha bodytec II, K182519
Secondary: Compex rehab, K090632

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.

miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions:

- Re-educating muscles
- Relaxation of muscle spasm

- Retarding or preventing disuse muscle atrophy

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.

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 setting incl. professional sport setting and stationary in closed rooms (clinics, hospitals, nursing homes, doctor's offices, physical therapists' private offices). 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/patient 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/patient 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/patient on specific exercises to perform. The training can be stopped anytime by pressing the multi-function / stop button.

Predicate Device Comparison

General

Characteristic	**New Device**	**Primary predicate device**	**Secondary Predicate Device**	**Similar / Different**
510(k) Number	K201975	K182519	K090632	-

Device Name, Model	miha bodytec II	miha bodytec II	Compex rehab	-
Manufacturer	miha bodytec GmbH	miha bodytec GmbH	Chattanoogah	-
Regulation Number	890.5850	890.5850	890.5850	Similar.
Product code	NGX; IPF	NGX	IPF	Different. The subject device combines both product codes NGX and IPF of the predicate devices within the same regulation number.
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. miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In Addition it is indicated for the following conditions: - Re-educating muscles - Relaxation of muscle spasm	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	The Compex® Rehab is an adjunctive multifunction electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES). The Compex® Rehab is indicated for the following conditions: - Re-educating muscles - Relaxation of muscle spasm	Similar between subject and primary predicate device in terms of indications for use NGX. The primary predicate device does not cover the IPF related therapeutic indications. Similar between subject and secondary predicate device in terms of indications for use IPF.

	- Retarding or preventing disuse muscle atrophy 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.	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	- Increasing local blood circulation - Retarding or preventing disuse atrophy - Maintaining or increasing range of motion	The secondary predicate device does not cover the NGX related muscle conditioning indications. However, despite the differences in indications, the general intended use, powered muscle stimulator for medical purposes, is the same. Moreover, the subject device combines both indications and does not add additional indications.

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 / 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 / control unit which is channel-wise connected to the respective electrodes	Similar electrode connection from a control unit to the attached electrodes
Power Source(s)	Control unit: 15 V - 19 V; External power supply (100 - 240 V ~ 50 - 60 Hz)	Control unit: 15 V - 19 V; External power supply (100 - 240 V ~ 50 - 60 Hz)	4.8 V (2000 mAh) NiMH rechargeable battery	No difference between subject and primary predicate device. Difference between subject and secondary predicate device. 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	Power Supply in accordance with IEC 60601-1	N/A (battery operated device)	No difference between subject and primary predicate device. Difference between subject and secondary predicate device. See comment on power source.
- Patient Leakage Current	< 100 µA	< 100 µA	N/A (battery operated device)	No difference between subject and primary predicate device. Difference between subject and secondary predicate device. See comment on power source.
- Normal condition	< 100 µA	< 100 µA	N/A (battery operated device)	No difference between subject and primary predicate device. Difference between

				subject and secondary predicate device. See comment on power source.
- Single fault condition	< 100 µA	< 100 µA	N/A (battery operated device)	No difference between subject and primary predicate device. Difference between subject and secondary predicate device. See comment on power source.
Number of Output Modes	One (symmetric biphasic) with 6 training programs	One (symmetric biphasic) with 6 training programs	One (symmetric biphasic)	Similar. All 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, channel selective stimulation**.** Maximum one channel is active at any time.	Four independent and individually adjustable channels that are electrically isolated from each other.	No difference between subject and primary predicate device. Difference between subject and secondary predicate device.

				However, a higher number of channels does not impose higher output values. It simply means that more muscles groups can be stimulated. Beside that, maximum 1 channel is active at any time.
- Synchronous or Alternating?	Alternating	Alternating	For 2-channel configuration, channels 1 and 2 alternate. For 4-channel configuration, channels 1+2 alternate with channels 3+4.	Similar. All devices provide an alternating output.
- Method of Channel Isolation	Multiplexed by control unit	Multiplexed by control unit	N/A	No difference between subject and primary predicate device. Corresponding information for secondary predicate device not

				publicly available.
Regulated Current or Regulated Voltage?	Regulated voltage (all channels)	Regulated voltage (all channels)	Regulated current (all channels)	No difference between subject and primary predicate device. Different regulation mechanism between subject and secondary predicate device. However, both are safe and effective and comply with IEC 60601-2-10.
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Similar
Automatic Overload Trip?	Yes, no load and short circuit conditions are handled	Yes, no load and short circuit conditions are handled	N/A	No difference between subject and primary predicate device. Corresponding information for secondary predicate device not

				publicly available.
Automatic No-Load Trip?	Yes, no load and short circuit conditions are handled	Yes, no load and short circuit conditions are handled	N/A	No difference between subject and primary predicate device. Corresponding information for secondary predicate device not publicly available.
Automatic Shut Off?	On/Off-Switch, stimulation stops after defined duration, automatic stop of stimulation in case of failure / malfunction detected	On/Off-Switch, stimulation stops after defined duration, automatic stop of stimulation in case of failure / malfunction detected	On/Off button to interrupt the programme momentarily, stimulation stops after defined duration, automatic stop of stimulation in case of failure / malfunction detected through regular automatic performance checks during operation	Similar. All 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 athlete/patient is supervised by a trainer and able to manipulate intensity (amplitude) and push the stop button	Yes, while a program is active the athlete/patient is supervised by a trainer and able to manipulate intensity (amplitude) and push the stop button	Operation only by authorized individuals. Choice of therapy parameters, programs and protocols only by responsible physician or therapist. During	No difference between subject and primary predicate device. Difference between subject and

			training not always supervised. Only if patients are unable to operate the emergency stop function.	secondary device, because supervision during training is not always mandatory for the secondary device. However, a continuous supervision of a trainer is expected to increase the safety of the device.
Indicator Display:	Yes	Yes	Yes	Similar, all devices provide a display.
- On/Off Status?	Yes	Yes	Yes	Similar, all devices show the on/off status.
- Low Battery?	N/A, no battery	N/A, no battery	Yes	Different. Not applicable to subject and primary predicate device since no battery is used.
- Voltage/ Current Level?	Yes, displayed in form of percentage / value range	Yes, displayed in form of percentage / value range	Yes, displayed in form of black bar graphs	Similar, all 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	Training should not exceed 20 minutes; Screen shows remaining time in minutes and displays image showing time remaining	Maximum = 20 minutes (for the programs referred to for substantial equivalence discussion); Screen shows remaining time in horizontal bars	No difference between subject and predicate devices.
Number of Programs	6 programs	6 programs	22	No difference between subject and primary predicate device. The secondary predicate device offers more programs. However, with the programs provided by the subject device, the indications stated are covered
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	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	The device is equipped with a keypad composed of push buttons which are located below the LCD. The function for each button is defined by a symbol on the LCD corresponding	Subject and primary predicate device are identical. Difference between subject and secondary predicate device.

	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)	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)	to the button immediately below it. The display is a graphic display capable of showing alpha numeric characters (including lower case characters), most standard ASCII symbols, and graphics appropriate to assist the user in selecting a desirable program. The LCD is used to display system information to the user.	However, subject device provides a larger display for changing settings, choosing programs / training plans, and providing relevant informatio n 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 use requires the qualified and trained operator.	Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator.	Mobile device	No difference between subject and primary predicate device. Difference between subject and secondary device.
Operator	The device must only be operated by a trainer, who received full training by miha bodytec.	The device must only be operated by a trainer, who received full training by miha bodytec.	Only authorised individuals are allowed to operate the device. Individuals are authorised after receiving training in the operation of the unit and reading this operating on manual.	Similar. Both devices require operation by a qualified operator who received a training in correspond

<table>
<tr><td></td><td></td><td></td><td></td><td>ing operation.</td></tr>
<tr><td>Compliance with 21 CFR 898?

(Mandatory since May 9, 2000)</td><td>Yes</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>
<tr><td>2 electrodes for sides of back</td><td>9.75</td><td>11.85</td></tr>
<tr><td>2 electrodes for lower back</td><td>14.4</td><td>19.47</td></tr>
</table>

<table>
<tr><td>Strap size</td><td>Electr. size in²</td></tr>
<tr><td>Size 1 (pair)</td><td>Each 34.15</td></tr>
<tr><td>Size 2 (pair)</td><td>Each 48.77</td></tr>
<tr><td>Size 3 (pair)</td><td>Each 64.36</td></tr>
</table>

<table>
<tr><td>Strap size</td><td>Electr. size in²</td></tr>
<tr><td>Size 1 (pair)</td><td>Each 14.7</td></tr>
</table></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

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<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>
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</table>

<table>
<tr><td>Strap size</td><td>Electr. size in²</td></tr>
<tr><td>Size 1 (pair)</td><td>Each 14.7</td></tr>
</table></td><td>Electrodes with pre-defined (supplied with the device) size from 3,88 in² to 7,78 in².
Length x Width of electrode pads:
1,97 in x 1,97 – 3,94 in</td><td>Same size between subject and primary predicate device. Electrodes have been cleared under K182519.

Difference between subject and secondary predicate. However, electrodes of subject device are bigger which leads to less current density and therefore to lower severity in case of harm.</td></tr>
</table>

	Size 2 (pair) Each 18.34	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.	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 a high friction, and forced fitting, mechanically shielded connector.	Identical between subject and primary predicate device. Different plug design between subject and secondary predicate device. 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 Compliant with protected lead wire and	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 Compliant with protected lead wire and	Each of the four 0,083 inch lead wires will connect the output of the stimulator to each of the electrodes for each respective output channel. These cables connect to the electrodes with snap fastener and connect to the machine with a high friction, and forced fitting, mechanically shielded connector.	No difference between subject and primary predicate device. Difference between subject and secondary predicate device because the cable leads from the control unit directly to the

	patient cable safety requirements	patient cable safety requirements		electrodes of the secondary predicate device. However, both devices have been successfully tested according to the relevant recognized safety standards (IEC 60601).
Conductivity of the electrodes	The athlete/patient 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 covers 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 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 covers 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.	Limited usage, gel-covered electrodes. After some usage, the quality of the electrodes, resistance and adherence will depend on the user's skin type. The electrodes are self-adhesive and need to be attached directly to the skin. They do not need to be moistened and are not allowed to be used on different patients due to direct skin contact	No difference between subject and primary predicate device. Electrodes have been cleared under K182519. Difference between subject and secondary device. However, both approaches are effective. The difference of miha bodytec II is that the electrodes must be moistened

				with water and do not have any direct skin contact.
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 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.	The single individual electrodes are not pre-placed in any kind and can be applied on any area of the body	No difference between subject and primary predicate device. Electrodes have been cleared under K182519. Difference between subject and secondary device. However, with miha bodytec II there is no risk of incorrect electrode placement 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.	The conductive electrode itself (under the textile) is made out of a 100% BEKINOX Stainless Steel multifilament yarn. No direct skin contact possible.	Direct skin contact. Further information not publicly available.	No difference between subject and primary predicate device. Electrodes have been cleared under K182519.
Maximum duration for	Max. 20 minutes per treatment.	Max. 20 minutes per treatment.	Maximum = 20 minutes (for the programs referred	No difference between

use per treatment			to for substantial equivalence discussion); Screen shows remaining time in horizontal bars	subject and predicate devices.
Accessories	i-body vest i-body strap i-body belt Undergarments Transponder card	i-body vest i-body strap i-body belt Undergarments Transponder card	Bags of small electrodes (5x5 cm 1 snap connection) 2 bags of large electrodes (5x10 cm 2 snap connections) Set of 4 pin cables Snap adaptor kit Motor point pen	No difference between subject and primary predicate device. Difference between subject and secondary predicate device. The secondary predicate device needs additional accessories for electrode placement.
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: 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: N/A Control unit: 0,66 lb (battery included) Accessory: N/A	No difference between subject and primary predicate device. Difference between subject and secondary predicate device.
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: 1.39 × 0.89 × 0.23 (W × D × H in ft) Complete: 1.77 × 1.69 × 3.89 (W × D × H in ft)	Control unit: 0.45 × 0.31 × 0.11 (W × D × H in ft)	No difference between subject and primary

				predicate device. Difference between subject and secondary predicate device.
Housing Materials and Construction	**Control unit:** Aluminum	**Control unit:** Aluminum	**Control unit:** plastic	No difference between subject and primary predicate device. Different housing material between subject and secondary predicate device. 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 60601-1-11:2015 IEC 60601-2-10:2016 IEC 62304:2006 + A1:2015	ISO 14971:2007 AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2015 IEC 60601-2-10:2016 IEC 62304:2006 + A1:2015	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Similar.

	IEC 62366-1:2015 + COR1:2016 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010 ASTM F1980-16	IEC 62366-1:2015 + COR1:2016 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010 ASTM F1980-16		

Table 1: Basic Device Characteristics – Comparison with Predicate Device

Output Specifications

Characteristic	New Device	Primary Predicate Device	Secondary Predicate Device	Similar / Different
Waveform	Symmetric biphasic	Symmetric biphasic	Symmetric biphasic	Similar output
Shape	Rectangular	Rectangular	Rectangular	Similar shape
Maximum Output Voltage	<= 74Vp @ 500Ω (54 - 74 Vp) <= 152Vp @ 2kΩ (110 … 152 Vp) <= 152Vp @ 10kΩ (130 … 152 Vp)	<= 74Vp @ 500Ω (54 - 74 Vp) <= 152Vp @ 2kΩ (110 … 152 Vp) <= 152Vp @ 10kΩ (130 … 152 Vp)	60V @ 500Ω	No difference between subject and primary predicate device. Different maximum output values between subject and secondary predicate device. 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)	< 148mAp @ 500Ω (108-148mAp) < 76mAp @ 2kΩ (55-76mAp) < 15 mAp @ 10kΩ (13-15mAp)	120mA @ 500Ω	No difference between subject and primary predicate device. Different maximum output current between subject and secondary predicate device. 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	50 - 400 µs	30 - 400 µs	Similar pulse width.
Frequency (Hz)	2 - 150 Hz	2 - 150 Hz	1 - 150 Hz	Similar frequency.
Symmetrical phases?	Yes	Yes	Yes	Similar.
Phase Duration	25 … 200 µs	25 … 200 µs	15 … 200 µs	Similar phase duration
Maximum Phase Charge	<32 µC @ 500Ω	<32 µC @ 500Ω	48 µC @ 500Ω	No difference between subject and primary predicate device.

				Different maximum phase charge between subject and secondary predicate device. However, subject device value is lower than the value of the secondary predicate device.
Maximum Current Density	0.64 mA/cm² @ 500Ω	0.64 mA/cm² @ 500Ω	1,18 mA/cm² @ 500Ω	No difference between subject and primary predicate device. Different maximum current density between subject and secondary predicate device. However, all devices fulfill the requirements of IEC 60601-2-10 because the values are within the limit of 2 mA/cm².
Maximum Power Density	0.82 mW/cm² @ 500Ω	0.82 mW/cm² @ 500Ω	N/A	No difference between subject and primary

				predicate device. Corresponding information for secondary predicate device not publicly available.
Burst Mode	Contraction time: 1 – 10 s Relaxation time: 0.0 – 10 s	Contraction time: 1 – 10 s Relaxation time: 0.0 – 10 s	N/A	No difference between subject and primary predicate device. Corresponding information for secondary predicate device not publicly available.
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, button for immediate shut off, redundant hardware error monitoring (emergency STOP option) Firmware self-tests.	N/A	No difference between subject and primary predicate device. Corresponding information for secondary predicate device not publicly available.

Table 2: Output Specifications – Comparison with Predicate Devices

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.

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 F1980-16. 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.

Performance Standards

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

- IEC 60601-2-10:2016 - 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 60601-1-11:2015 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62304:2006 + A1:2015 - Medical Device Software - Software Life Cycle Processes
- ISO 14971:2007 - Medical Devices - Application Of Risk Management To Medical Devices

- IEC 62366-1:2015 + COR1:2016 - 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
- ASTM F1980-16 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

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 27, 2019

Conclusion

All features and technological characteristics of the subject and primary predicate device are identical, despite the indications for use. Electrodes have been cleared under K182519. Miha bodytec II has similar indications for use as the primary and the secondary predicate device combined and similar technological characteristics and features as the secondary predicate device. All 3 devices use wired connections between the control unit to the electrodes. Miha bodytec II and the primary predicate device use the same specifically designed biocompatible undergarment and electrode connector accessories which are placed on the undergarment and not directly on the skin while the secondary predicate device uses self-adhesive electrodes which get placed directly on the skin.
The devices have slightly different output specifications, cable specifications, however, all within the limits given by IEC 60601-2-10 and in compliance with IEC 60601-1 and IEC 60601-1-2. Both miha bodytec II and the primary predicate device are powered by line voltage, whereas the Compex Rehab 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.
miha bodytec II provides a slightly different user interface with an integrated 10.1 inch display. Usability tests for miha bodytec II have been successfully conducted following FDA's guidance.
None of these differences raise any new issues regarding safety or effectiveness. Therefore, we conclude that miha bodytec II is substantially equivalent to the primary predicate device miha bodytec II as well as the secondary predicate device Compex Rehab.