February 23, 2023

Neuro20 Technologies
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K223797
Trade/Device Name: Neuro20 Pro System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX, IPF
Dated: January 25, 2023
Received: February 6, 2023

Dear Dave Yungvirt:

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

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

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

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

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

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223797

Device Name
Neuro20 PRO System

Indications for Use *(Describe)*
The Neuro20 PRO System is intended to stimulate muscles in order to improve or facilitate muscle performance.

Other indications for use include:
- Re-educating muscles
- Increasing local blood circulation
- Maintaining or increasing range of motion
- Relaxation of muscle spasm
- Retarding or preventing disuse atrophy

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

510(k) Submitter:

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Date 510(k) Summary Prepared 15-July-2022

Trade Name of Device: Neuro20 PRO System
Common Name: Neuro20 PRO
Model Identification: N20PRO-SYS
Product codes: NGX, IPF
Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning
(21CFR 890.5850, Product Code NGX)
Stimulator, Muscle
(21CFR 890.5850, Product Code IPF)

Review Panel 89 Physical Medicine

Predicate devices

Primary Predicate Device:	miha bodytec II
510(k) Number:	K201975
Product Classification:	II
Classification Name:	Powered Muscle Stimulator (21CFR 890.5850, Product Code NGX, IPF)
Secondary Predicate Device:	Compex® Rehab
510(k) Number:	K090632
Product Classification:	II
Classification Name:	Powered Muscle Stimulator (21CFR 890.5850, Product Code IPF)

Device Description:

The Neuro20 PRO System is a powered muscle stimulator designed for individual or group rehabilitation and recovery. The Neuro20 PRO System is a transcutaneous electrical muscle stimulation (EMS) device which stimulates motor nerves by means of electrical impulses transmitted by electrodes. The system utilizes electrical stimulation to create an involuntary contraction. The excitations of motor neurons 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. The involuntary muscle activation can be voluntarily over-ridden through intentional exercise. Individual intensity levels can be modulated for each muscle group. One to ten patients may be treated within a session.

Device Description (continued)

The Neuro20 PRO System is comprised of three major components: the Control Box with battery (the muscle stimulator), Smart Suit (the wearable suit with electrodes covering the muscles), and Operating Tablet with software which allows the medical professional to adjust the parameters for the patient. Users may be actively engaged within a variety of training modes while the clinician/operator controls the software. The Neuro20 PRO System accessories are a battery charger, protective case, and Smart Suit packaging.

The Neuro20 Control Box connects to the suit and is powered by a battery. It is controlled by the medical practitioner operating the software. The Smart Suit applies the electrodes to the upper body, arms, legs, and buttocks. The Control Unit is connected to the Operating Tablet wirelessly.

The Neuro20 PRO System is to be used in a professional setting such as physicians' office, physical therapist, professional sports setting, and nursing homes as well as in the home healthcare environment. The device must be operated by a trainer who has received full training from the manufacturer. Prior to a training session the correct suit size is selected for the patient in order to ensure proper placement of the electrodes. The trainer can choose between pre-set training programs on the software. The intensity can be adjusted by the trainer at the UI of the Operating Tablet separately for each channel. Complete body training which addresses all muscle groups is possible with up to 10 pairs of electrodes. Once the training is started, the control unit generates and transmits the electrical signals to the electrodes via Bluetooth. During pulse application, the trainer instructs the patient on specific exercises to perform. The training can be stopped anytime by pressing the multi-function / stop button, pause button on the software, or on the Control Box connected to the Suit.

Indications for Use of the Device:

The Neuro20 PRO System is intended to stimulate muscles in order to improve or facilitate muscle performance.

Other indications for use include:
- Re-educating muscles
- Increasing local blood circulation
- Maintaining or increasing range of motion
- Relaxation of muscle spasm
- Retarding or preventing disuse atrophy

The following table compares the indications for use of the proposed device against those of the primary predicate device and the secondary predicate device.

Neuro20 PRO System	**miha bodytec II**	**Compex® Rehab**
The Neuro20 PRO System is intended to stimulate muscles in order to improve or facilitate muscle performance. Other indications for use include: - Re-educating muscles - Increasing local blood circulation - Maintaining or increasing range of motion - Relaxation of muscle spasm - Retarding or preventing disuse atrophy	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.	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 * Increasing local blood circulation * Retarding or preventing disuse atrophy * Maintaining or increasing range of motion

Technological Characteristics Comparison with Predicates:

The design and material differences between the Neuro20 PRO System, the primary predicate and secondary predicate is that the Neuro20 PRO System design is a complete body suit made of flexible spandex with electrodes that do not contain accessible plugs or cables but does contain a battery pack with rechargeable Bluetooth technology. The miha bodytec II uses external power supply to operate and involves the use of an i-body® electrode polyurethane vest worn by the patient, with electrodes worn over under garments and a control unit mounted on a stand, connected with the control unit via cables. The Compex® Rehab is a battery-powered hand-held stimulator which connects to cutaneous electrodes, placed manually on the body part being targeted (including the same body parts as those targeted by the Neuro20 PRO System and miha bodytec II).

In summary for energy comparison between the Neuro20 PRO System, the primary predicate and secondary predicate, and miha bodytec II, the Neuro20 PRO has less maximum output voltage, output current, power density and phase charge than the primary predicate and secondary predicate miha bodytec II. The Neuro20 PRO system is within the pulse width, pulse frequency, and pulse duration range of the primary predicate and secondary predicate. miha bodytec II . The waveforms of the Neuro20 PRO System, the primary predicate and secondary predicate and the miha bodytec II are similar. The Neuro20 PRO System has more safety options then the primary predicate and secondary predicate miha bodytec II in that the Neuro20 PRO System connector layout is designed to prevent misconnection, current regulation, no charging of the device is possible while training (removal of accumulator), fuses and lock bits against manipulation, battery, voltage, and output current monitoring.

Technological Characteristics Comparison with Predicates: (continued)

Characteristic	Neuro20 PRO System Proposed device	miha bodytec II Primary predicate	Compex® Rehab Secondary predicate
1. 510(k) Number	K223797	K201975	K090632
2. Device Name, Model	Neuro20 PRO System	miha bodytec II	Compex® Rehab
3. Manufacturer	Neuro20 Technologies, Corp.	miha bodytec GmbH	Chattanooga Group
4. Power Source(s)	Rechargeable Li-ion battery 7.4V Types LP-E5, 2 Cells each UL listed: MH60905. Pack certified to IEC62133-2:2017 (5.6 watts (756 mA Max @ 7.4 V).	Control Unit: 15V – 19V; External power supply (100-240V ~ 50 – 60 Hz).	4.8 V (2000 mAh) NiMH rechargeable battery
- Method of Line Current Isolation	N/A – Neuro20 PRO System is a battery-operated device in accordance with 60601-1-1	Power Supply in accordance with IEC 60601-1-1	N/A (battery operated device)
- Patient Leakage -- Normal Condition -- Single Fault Condition	N/A – Neuro20 PRO System is a battery-operated device in accordance with 60601-1-1	< 100 µA	N/A (battery operated device)
5. Number of Output Modes	4 output modes	One (symmetric biphasic) with 6 training programs.	One (symmetric biphasic)
6. Number of Output Channels	10 channels selective stimulation.	10 channels, selective stimulation. Maximum one channel is active at any time.	Four independent and individually adjustable channels that are electrically isolated from each other
- Synchronous or Alternating	Synchronous, but never two channels activated at the same time.	Alternating.	For 2-channel configuration, channels 1 and 2 alternate. For 4-channel configuration, channels 1+2 alternate with channels 3+4.
- Method of Channel Isolating	Multiplexed by Control Box	Multiplexed by control unit.	*Not publicly available*
7. Regulated Current or Regulated Voltage?	Constant current control	Regulated voltage (all channels)	Regulated current (all channels)

Characteristic	Neuro20 PRO System Proposed device	miha bodytec II Primary predicate	Compex® Rehab Secondary predicate
8. Software/ Firmware/ Microprocessor Control	Yes	Yes	Yes
9. Automatic Overload Trip	Yes, no load and short circuit conditions are handled	Yes, no load and short circuit conditions are handled	*Not publicly available*
10. Automatic No Load Trip	Yes, no load and short circuit conditions are handled.	Yes, no load and short circuit conditions are handled.	*Not publicly available*
11. Automatic Shut Off	"On/Off" switch and automatic shut off after 4 minutes without communication, 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.
12. Patient Override Control	Yes, Stop button located on the Neuro20 Control Box, patient has direct access.	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 training not always supervised. Only if patients are unable to operate the emergency stop function.
13. Indicator Display: - On/Off Status	Yes	Yes	Yes
- Low Battery	Yes	N/A – No Battery.	Yes
- 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
14. Timer Range (in minutes)	5 seconds – 1 hour. 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

Characteristic	Neuro20 PRO System Proposed device	miha bodytec II Primary predicate	Compex® Rehab Secondary predicate
15. Compliance with Voluntary Standards	ISO 14971 :2019 IEC 60601-1 2005 +A1 :2012 EN 60601-1-2 : 2020-9 FCC/CFR 47 :Part 15B IEC60601-2-10 :2012+AMD1 :2016 IEC 62304 :2006+AMD1 :2015 IEC 62366-1 :2015+AMD1 :2020 ISO 10993-1:2018 ISO 10993-10:2010 IEC 60601-1-6: 2010+AMD 2:2020 ISO 15223-1:2016 IEC 62133-2:2017 IEC 60601-1-11: 2020-7 ISO 10993-5: 2009	ISO 14971:2007 AAMI ANSI ES 60601-1_2005/®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 62366-1:2015 + COR1:2016 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010 ASTM F1980-16	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10
16. Compliance with 21 CFR 898	Yes.	Yes.	Yes
17. Weight	Neuro20 Control Box: 160g with battery Neuro20 Operating Tablet: Variable. Neuro20 Smart Suit Dependent on clothing size.	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
18. Dimensions (in.) [WxDxH]	Neuro20 Control Box: 126 mm x 75.5 mm x 37.6 mm Neuro20 Operating Tablet: Variable. Neuro20 Smart Suit: Dependent on clothing size	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)
19. Housing Material and Construction	Control Box: ABS plastic housing.	Control unit: Aluminum.	Control unit: plastic

Substantial Equivalence Discussion (continued)

Output Specifications:

Characteristic	**Neuro20 PRO System Proposed device**	**miha bodytec II Primary predicate**	**Compex® Rehab Secondary predicate**
Waveform (e.g., pulsed monophasic, biphasic)	Symmetric biphasic	Symmetric biphasic.	Symmetric biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal	Rectangular.	Rectangular.	Rectangular
Maximum Output Voltage	55V @ 500Ω (+/- 10%) 55V @ 2kΩ (+/- 10%) 55V @ 10kΩ (+/- 10%)	<= 74Vp @ 500Ω (54 - 74 Vp) <= 152Vp @ 2kΩ (110 … 152 Vp) <= 152Vp @ 10kΩ (130 … 152 Vp)	60V @ 500Ω *Information for 2kΩ and 10kΩ not publicly available.*
Maximum Output Current	120 mA @ 500Ω 30 mA @ 2kΩ 6 mA @ 10kΩ	< 148mAp @ 500Ω (108-148mAp) < 76mAp @ 2kΩ (55-76mAp) < 15 mAp @ 10kΩ(13-15mAp)	120mA @ 500Ω *Information for 2kΩ and 10kΩ not publicly available.*
Pulse Width	150 - 400 µs	50 - 400 µs	30 - 400 µs
Frequency	7 - 100Hz (5% accuracy)	2 - 150 Hz	1 - 150 Hz
For interferential modes - Beat frequency	N/A – no interferential modes	*Not publicly available*	*Not publicly available*
Multiphasic Waveform: - Symmetrical Phases?	Yes	Yes	Yes
- Phase Duration	75 – 200 µs (10% accuracy)	25 … 200 µs	15 … 200 µs
Net Charge (if zero, state method of achieving zero net charge).	0µC @500Ω Excitation pulse fully Compensated	*Not publicly available*	*Not publicly available*
Maximum Phase Charge	24 µC @500Ω	<32 µC @500Ω	48 µC @ 500Ω

Maximum Current Density	0.46 mA/cm2 @ 500Ω RMS	0.64 mA/cm² @ 500Ω	1,18 mA/cm² @ 500Ω
Maximum Power Density	4.7 mW/cm^2 @ 500Ω RMS	0.82 mW/cm² @ 500Ω	*Not publicly available*
Burst Mode - Pulses per burst	N/A – no burst mode	*Not publicly available*	*Not publicly available*
- Burst per second	N/A – no burst mode	*Not publicly available*	*Not publicly available*
- Burst duration (seconds)	N/A – no burst mode	Contraction time: 1 – 10 s Relaxation time: 0.0 – 10 s	*Not publicly available*
- Duty Cycle [Line (b) x Line (c)]	N/A – no burst mode	*Not publicly available*	*Not publicly available*
ON Time	1-60 seconds	See Burst Mode	*Not publicly available*
OFF Time	0-60 seconds	See Burst Mode	*Not publicly available*
Additional features: safety Circuits	Short circuit protection, no load and overload protection, power button for immediate shut-off, hardware error monitoring, firmware self- tests, security connection between Neuro20 Control Box and Neuro20 Smart Suit for an immediate cessation of training if wrongly connected, connector layout is designed to prevent misconnection, current regulation, no charging of device possible while training (removal of accumulator), fuses and lock bits against manipulation, battery, voltage, and output current monitoring	Short circuit monitoring, watch dog monitoring, no load trip, on load trip, button for immediate shut-off, redundant hardware error monitoring, (emergency stop option). Firmware self -tests	*Not publicly available*

Determination of Substantial Equivalence:

Non-Clinical Performance Data:

The following non-clinical tests were performed on the Neuro20 PRO System:

Performance Standard Neuro20 PRO System	Performance Standard Test Results
IEC60601-2-10:2012+AMD1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	Passed IEC60601-2-10 Standard Testing.
IEC 60601-1-2:Edition 4.1, 2020-09; Consolidated Version: Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests FCC/CFR 47:Part 15B	Passed IEC 60601-1-2 Standard Testing.
IEC60601-1:2005+A1:2012 – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Passed IEC 60601-1 Standard Testing.
IEC 60601-1-11:Edition 2.1, 2020-07, Consolidated Edition :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	Passed IEC 60601-1-11 Testing:
IEC 62304:2006+AMD1:2015 Medical Device Software - Software life-cycle processes	Checklist of Compliance IEC 62304 accepted.
EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	Risk Management per ISO 14971 performed.
IEC 62366-1:2015+AMD1:2020 Medical Devices – Part 1: Application of usability engineering to medical devices	Passed IEC 62366-1 Standard Testing.
ISO10993-1:2018 – Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	ISO 10993-1 Evaluation Performed.
ISO 10993-5:2009 – Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Biological Evaluation 10993-5 performed.
ISO10993-10:2010 – Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Passed ISO-10993-10 Standard Testing.
IEC60601-1-6:2010+AMD2:2020 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	Passed IEC 60601-6 Standard Testing. Passed IEC 62366-1 Standard Testing.
IEC 62133-2:2017 – Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	Passed IEC 62133-2 Standard Testing.

Determination of Substantial Equivalence: (continued)

Non-Clinical Performance Data: (continued)

In summary, an evaluation of the results of the non-clinical testing performed on the Neuro20 PRO System demonstrates that the proposed device's safety, effectiveness, performance and functionality.

Clinical Performance Data:

The determination of substantial equivalence using clinical performance data is not applicable because such data is not required to determine the substantial equivalence of the Neuro20 PRO System to the cited predicate devices.

Conclusion

In conclusion, based on the nonclinical tests and the comparison offered in this 510(k) submission, it is demonstrated the Neuro20 PRO System is as safe, as effective, and performs as well as or better than the legally marketed devices identified in this submission.