March 03, 2022

MyndTec Inc.
Yesmil Pena
Quality Assurance Manager
1900 Minnesota Court Suite 122
Mississauga, Ontario
Canada

Re: K212149
Trade/Device Name: MyndMove 2.0
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: January 18, 2022
Received: January 20, 2022

Dear Yesmil Pena:

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,

Amber Ballard, PhD
Assistant Director
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)*

K212149

Device Name

MyndMove 2.0

Indications for Use *(Describe)*

MYNDMOVE is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES)

Improvement of arm and hand functions and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C3-T1 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES)

- Maintenance and/or increase of arm and hand range of motion
- Prevention and/or retardation of disuse atrophy
- Increase in local blood circulation
- Reduction of muscle spasm
- Re-education of muscles.

MyndMove therapy can only be administered by Occupational or Physical Therapy professionals that have completed MyndMove training by MyndTec on the use of the MyndMove System.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter / Owner Information

MyndTec Inc.
1900 Minnesota Court, Suite 122
Mississauga, Ontario
Canada, L5N 3C9

Contact Person

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Date Prepared:

March 02, 2022

Device Identification

A. Name of Device	MyndMove System and MyndMove Functional Electrical Stimulator
B. Classification Name	External Functional Neuromuscular Stimulator and Powered Muscle Stimulator
C. Proprietary Name	MyndMove 2.0
D. Device Classification	Class II
E. Panel	Neurology
F. Device Product Code	GZI and IPF
G. Regulation Number	882.5810 External functional neuromuscular stimulators, and 890.5850 Powered Muscle stimulators
H. Previous FDA Status	no prior FDA Status
I. Basis for Submission	Modified Device

Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
MyndMove	MyndTec Inc.	K170564	August 30, 2017

Device Description

The purpose of this Traditional 510(k) is to obtain clearance for MyndMove 2.0, a modified version of the MyndMove device (K170564) functional electrical and neuromuscular

stimulation device. The MyndMove device (K170564) has undergone minor modifications resulting in the MyndMove 2.0 version. The modifications are a change of the stimulator tablet material due to availability, the removal of the internal battery from the design of the MyndMove 2.0, the addition of IP22 rated ingress protection and the addition of an optional cart to facilitate mobility in the clinical environment. A slight change in the final paragraph after the indications for use to add Physiotherapist Assistants (PTAs) and Occupational Therapy Assistants (OTAs) in addition to Physiotherapists (PTs) and Occupational Therapists (OTs) as authorized users of the MyndMove 2.0 upon training and licensing by State Law, in alignment with Medicare and TRICARE policies.

The MyndMove 2.0 System is a neuromodulation device that delivers short electrical pulses to stimulate muscle contractions and enhance motor recovery following Stroke or Spinal Cord Injury. The MyndMove system comprises the Stimulator device, stimulation electrodes and cables, hand and foot switches, and integrated software.
The MyndMove 2.0 Functional Electrical Stimulator is an eight-channel device with a touch screen user interface (UI). The Stimulator software allows the User to choose from a number of pre-programmed stimulation protocols, to customize the stimulation intensities for each patient, and to document the treatments provided.

Each MyndMove Stimulator is connected, via an IEEE 802.11 a/b/g/n wireless radio adapter, to a cloud-based backend data management system. The primary function of the backend is to manage the various elements of the MyndMove ecosystem including but not limited to patient unique IDs and prescriptions, therapist profiles and stimulation protocols. MyndMove 2.0 Therapy can only be administered by trained MyndMove Therapy professionals (TMMT) with assigned Therapist Log-In IDs. TMMTs are Occupational or Physical Therapy professionals that have completed MyndMove training by MyndTec on the use of the MyndMove system.

MyndMove 2.0 uses surface electrical stimulation to produce muscle contractions in different combinations to achieve a wide range of reaching and grasping functions. To achieve these movements, the single use electrodes are placed in various combinations on the surface of muscles in the arm and hand.

MyndMove 2.0 is based on advanced functional electrical stimulation (FES) principles designed to promote neuroplasticity by influencing the efferent and afferent pathways. Proper sequencing of the muscle contractions as per the MyndMove 2.0 protocols achieve a wide range of reaching and grasping functions. During the delivery of MyndMove 2.0 therapy, the patient executes functional tasks with assistance from the therapist and the MyndMove 2.0 device. The patient attempts to perform the movement and is then assisted to complete the movement when the therapist activates the MyndMove 2.0 stimulation protocol, which generates bursts of short electrical pulses, using surface electrodes, to produce muscle contraction. In this manner, the patient gets both efferent and afferent input as they are actively attempting move and as the arm and/or hand is moved into the instructed position. Non-damaged pathways can be activated and non-damaged areas of the central nervous system can be trained to substitute for injured areas.

Indications for Use

MYNDMOVE 2.0 is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES)

Improvement of arm and hand functions and active range of motion in patients with hemiplegia due to stroke or upperlimb paralysis due to C3-T1 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES)

- Maintenance and/or increase of arm and hand range of motion
- Prevention and/or retardation of disuse atrophy
- Increase in local blood circulation
- Reduction of muscle spasm
- Re-education of muscles.

MyndMove therapy can only be administered by Occupational or Physical Therapy professionals that have completed MyndMove training by MyndTec on the use of the MyndMove System.

Type of Use

Prescription Use (Rx)

Performance Standards

MyndMove 2.0 complies with the current medical electrical equipment electromagnetic compatibility basic safety and performance, and software standards listed below, as verified upon Third Party testing for compliance with 60601-2-10 Edition 2.1 2016-04, (basic safety and essential performance of nerve and muscle stimulators), ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (basic safety and essential performance); 60601-1-2 Edition 4.0 2014-02 (basic safety and essential performance for Electromagnetic disturbances); 60601-1-11 Edition 2.0 2015-01(basic safety and essential performance requirements for medical electrical equipment a used in the home healthcare environment). MyndMove also complies with IEC 62304:2006 Medical device software - Software life cycle processes and 60601-1-6:2010 Third Edition + A1:2013 (basic safety and essential performance for usability). No additional usability testing to the original cleared device was required. There was no change to the hardware or software design. Performance testing was performed also internally against the same specifications of the cleared device.

As part of performance testing, six oscilloscope tracings were generated for 500 ohm, 2k ohm and 10k ohms and include output mode, amplitude, amplitude baseline, load resistance, pulse width, and electrode surface area with the corresponding maximum power density and average current density per surface area. The maximum net charge per pulse and phase charge for the modified device MyndMove 2.0 are identical to those of the cleared device MyndMove. The net charge per pulse for both the modified and cleared devices is 1.85 µC, and the maximum phase charge is 9.02 µC.

FDA Recognition No.	Standard Title
17-16	IEC 60601-2-10 Edition 2.1 2016-04. Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
19-4	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

19-8	IEC 60601-1-2 Edition 4.0 2014-02: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
19-14	IEC 60601-1-11 Edition 2.0 2015-01: 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.

Basis for Substantial Equivalence

MyndTec Inc.'s MyndMove and MyndMove 2.0 are similar in design, function and technical specifications. Both devices have the same intended use and deliver functional electrical and neuromuscular stimulation using coded therapeutic algorithmic protocols using an eight-channel stimulator with a maximum 20 mA output current for all 9cm x 5cm, 5cm x 5cm, 2.5cm diameter and 1cm x 3cm single use electrodes. Both the cleared and modified device have almost identical technical specifications as illustrated in the table below.

MyndMove 2.0 is the result of the removal of the battery, an upgrade of the tablet PC and other modifications to meet home use requirements, maximum current equal to all electrodes, the addition of scapula protocols, and the addition of an optional cart. The predicate device MyndMove has maximum outputs for electrodes depending on size, ranging from 5mA for a 3cm2 electrode, the smallest size, to 20mA for a 45cm2 electrode, the largest size. The modified MyndMove 2.0 applies a maximum 20 mA output current for all electrodes regardless of electrode size to enable the therapist to select the peak currents to generate full muscle recruitment with any electrode size, particularly with denervated muscles. In both the predicate and modified devices, peak current values for all electrode sizes fall under the 2mA/cm maximum allowed by IEC 60601-2-10. Scapula protocols were added to the existing deltoid anatomical sites to optimize patient objectives. An analysis of the performance testing results and all similarities and differences listed in the table below

leads to determine that the modified MyndMove 2.0 has the same technical characteristics the cleared MyndMove. The differences do not raise any concerns regarding safety and effectiveness. Therefore, MyndMove 2.0 is substantially equivalent to the predicate device, the cleared MyndMove.

Substantial Equivalence discussion for subject device MyndMove 2.0 and predicate device MyndMove.			
	Cleared Device MyndMove	**Modified Device MyndMove 2.0**	**SE Comparison**
510(k) Number	**K170564**	**(To Be Assigned)**	
Indications for Use	MyndMove is an electrical stimulation device indicated for the following uses: Functional electrical stimulation (FES)	MyndMove is an electrical stimulation device indicated for the following uses: Functional electrical stimulation (FES)	Identical

	Improvement of arm and hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C3-T1 spinal cord injury. NeuroMuscular Electrical Stimulation (NMES) • maintenance and/or increase of arm and hand range of motion, • prevention and/or retardation of disuse atrophy, • increase in local blood circulation, • reduction in muscle spasm, and • re-education of muscles. MyndMove therapy can only be administered by **Occupational or Physical Therapists** that have completed MyndMove training by MyndTec on the use of the MyndMove System.	Improvement of arm and hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C3-T1 spinal cord injury. NeuroMuscular Electrical Stimulation (NMES) • maintenance and/or increase of arm and hand range of motion, • prevention and/or retardation of disuse atrophy, • increase in local blood circulation, • reduction in muscle spasm, and • re-education of muscles. MyndMove therapy can only be administered by **Occupational or Physical Therapy professionals** that have completed MyndMove training by MyndTec on the use of the MyndMove System.	(There was a minor change on the last statement from 'Occupational or Physical Therapists' to 'Occupational or Physical Therapy professionals' to enable Occupational or Physical Therapy Assistants (OTAs or PTAs) to administer the MyndMove therapy with the appropriate training and per the corresponding jurisdiction laws and regulations).This change does not alter the intended use.
Anatomical Sites for Stimulation (Upper Limb)	**The MyndMove System stimulates the following Muscles:** **Extensor Digitorum, Extensor Carpi Radialis & Extensor Carpi Ulnaris** **Thenar Eminence (Opponens Pollicis Brevis, Flexor Pollicis Brevis & Abductor Pollicis Brevis)** **Flexor Digitorum Superficialis and Flexor Digitorum Profundus** **Biceps** **Triceps** **Posterior Deltoid, Middle Deltoid, and Anterior Deltoid** **Pectoralis Major** **1st, 2nd, and 3rd Lumbricals** **2nd Dorsal Interosseous**	**The MyndMove System stimulates the following Muscles:** **Extensor Digitorum, Extensor Carpi Radialis & Extensor Carpi Ulnaris** **Thenar Eminence (Opponens Pollicis Brevis, Flexor Pollicis Brevis & Abductor Pollicis Brevis)** **Flexor Digitorum Superficialis and Flexor Digitorum Profundus** **Biceps** **Triceps** **Posterior Deltoid, Middle Deltoid, and Anterior Deltoid** **Pectoralis Major** **1st, 2nd, and 3rd Lumbricals** **2nd Dorsal Interosseous** **Serratus Anterior, Lower Trapezius, Upper Trapezius (Scapula)**.	Equivalent Please refer to the Scapula protocol addition discussion below.
Where Used	Used for therapy sessions in a clinical setting only.	Used for therapy sessions in a clinical setting and for home use by a qualified user.	Equivalent MyndMove 2.0 was designed for and tested against 60601-1-11 (home healthcare)
Regulated current or regulated voltage?	Current Regulated	Current Regulated	Identical
Software/ firmware/ microprocessor control? (yes/no)	Yes	Yes	Identical
Automatic overload trip? (yes/no)	Yes	Yes	Identical
Automatic no- load trip? (yes/no)	Yes	Yes	Identical
Automatic shut off? (yes/no)	Yes	Yes	Identical
User override control? (yes/no)	Yes	Yes	Identical
Indicator display:	Yes	Yes	Identical
– On/off status? (yes/no)	Yes	Yes	Identical
– Low battery? (yes/no)	Yes	Yes	Identical
– Voltage/current level? (yes/no)	Yes	Yes	Identical
Timer range (minutes)	Stimulation time controlled by user. Max duration of stimulation program = 120 minutes (configurable in the backend)	Stimulation time controlled by user. Max duration of stimulation program = 120 minutes (configurable in the backend)	Identical

Compliance with voluntary standards? (if yes, specify)	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-2-10	Equivalent
Compliance with 21 CFR 898? (yes/no)	Yes	Yes	Identical
Power Sources	Mains OR Rechargeable Li-Ion Battery. Rechargeable Li-Ion: 14.8 V DC, 2000 mAh Power Supply Input: 100-240 V AC, 1.2A, 50-60 Hz Power Supply Output: 24 V DC, 4.16 A, 100W	AHM100PS24C2-8 manufactured by XP-Power 100-240 V AC, 1.2 A, 50-60 Hz 24 V DC, 4.16 A, 100 W Tripp Lite P012-006, 1-15P to C7 -10A, 120V, 18 AWG, 6 ft., Black Sabic, Lexan Polycarbonate : Sabic, Lexan Polycarbonate Sabic, Lexan Polycarbonate Covestro, Makrolon 2805 Polycarbonate TPE E4001-40-J02	Equivalent
Method of line current isolation	Galvanic Isolation (transformer) 4000 VAC	Galvanic Isolation (transformer) 4000 VAC	Identical
Normal condition (uA)	Earth Leakage: < 500 uA Lead to Ground: < 100 uA	Earth Leakage: < 500 uA Lead to Ground: < 100 uA	Identical
Single fault condition (uA)	Earth Leakage: < 1000 uA Lead to Ground: < 500 uA Patient on Mains: < 5000 uA	Earth Leakage: < 1000 uA Lead to Ground: < 500 uA Patient on Mains: < 5000 uA	Identical
Average DC current through electrodes when device is on but no pulses are being applied (uA)	Patient auxiliary current: Normal condition: < 100 uA Single fault condition: < 500 uA	Patient auxiliary current: Normal condition: < 100 uA Single fault condition: < 500 uA	Identical
Number of output modes (ie. Number of stimulation protocols)	Two Modes (applicable to all 33 stimulation protocols): - Biphasic Symmetric - Biphasic Asymmetric	Biphasic Asymmetric	Similar
Number of output channels	8	8	Identical
Synchronous or Alternating?	Asynchronous (channels are staggered)	Asynchronous (channels are staggered)	Identical
Method of channel isolation	Galvanic isolation (transformer): 1500VAC/3kV DC	Galvanic isolation (transformer): 1500VAC/3kV DC	Identical
Weight (lbs., oz.)	14lbs 6oz.	14lbs 6oz.	Identical
Dimensions (in.) [W x H x D] (including accessories)	Stimulator: 9.0 in x 4.3 in x 9.8 in	Stimulator: L 33 cm x W 25 cm x H 13.5 cm	Similar
Housing materials and construction (including accessories)	Stimulator Housing Materials: - Enclosure = Lexan PCB HPX4R - Plastic Bezel = ABS Plastic - Rubber Membrane = Silicone	Stimulator Housing Materials: - Enclosure = Lexan PCB HPX4R - Plastic Bezel = ABS Plastic - Rubber Membrane = Silicone	Identical
Additional Features (specify, if applicable)	- Timing of stimulation controlled by user (therapist) through the use of a hand or foot switch	- Timing of stimulation controlled by user (therapist) through the use of a hand or foot switch	Identical
Design and Human Factors	- Functional Electrical Stimulator. - Single Use Gel Electrodes - 8 stimulation channels, up to 16 electrodes. - Controlled by an embedded touch screen graphical user interface and hand and foot switches. - Preprogrammed with stimulation protocols. - No fitting required, instruction for electrode placement for each stimulation protocol included in user interface. - Used by Clinician Only.	– Functional Electrical Stimulator. – Single Use Gel Electrodes – 8 stimulation channels, up to 16 electrodes. – Controlled by an embedded touch screen graphical user interface and hand and foot switches. – Preprogrammed with stimulation protocols. – No fitting required, instruction for electrode placement for each stimulation protocol included user interface. – Used by Clinician Only	Identical
Biphasic Symmetrical Output Mode			
Waveform (eg. Pulsed monophasic, biphasic)	Balanced Biphasic Symmetrical	Not Applicable, No Symmetrical Output Mode	Equivalent
Shape (eg.	Rectangular	Not Applicable, No Symmetrical Output Mode	Equivalent

Rectangular, spike, rectified sinusoidal)			
Maximum Output Voltage (volts) (+/- %) at 500ohms, 2kohms and 10kohms	(+/- 10%) @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V	Not Applicable, No Symmetrical Output Mode	Equivalent
Maximum Output Current (specify units) (+/- %) at 500 ohms, 2kohms and 10kohms	(+/- 10%) @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA	Not Applicable, No Symmetrical Output Mode	Equivalent
Pulse width (specify units)	Positive: 150-400 us Negative: 150-400 us	Not Applicable, No Symmetrical Output Mode	Equivalent
Frequency (Hz)	1Hz or 40Hz	Not Applicable, No Symmetrical Output Mode	Equivalent
For multiphase waveforms only:			
Symmetrical phases? (yes/no)	Yes	Not Applicable, No Symmetrical Output Mode	Equivalent
Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	Positive: 150-400 us Negative: 150-400 us	Not Applicable, No Symmetrical Output Mode	Equivalent
Net Charge (uC per pulse) (If zero, state method of achieving zero net charge)	2.00 uC	Not Applicable, No Symmetrical Output Mode	Equivalent
Maximum Phase Charge (uC)	9.02 uC	Not Applicable, No Symmetrical Output Mode	Equivalent
Maximum Current Density (RMS) (mA/cm2)	1.36 mA/cm2 (for 1cm x 3cm electrode)	Not Applicable, No Symmetrical Output Mode	Equivalent
Maximum Power Density, (W/cm2), (using smallest electrode conductive surface area)	0.044W/cm2	Not Applicable, No Symmetrical Output Mode	Equivalent
Burst Mode (ie. Pulse trains):	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	Equivalent
Pulses per burst	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	Equivalent
Bursts per second	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	Equivalent
Burst duration (seconds)	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	Equivalent
Duty Cycle: Line (b) x Line (c)	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	Equivalent
ON Time (seconds)	Not Fixed - User Controlled	Not Applicable, No Symmetrical Output Mode	Equivalent
OFF Time (seconds)	Not Fixed - User Controlled	Not Applicable, No Symmetrical Output Mode	Equivalent
Biphasic Asymmetrical Output Mode			
Waveform (eg. Pulsed monophasic, biphasic)	Balanced Biphasic Asymmetrical	Balanced Biphasic Asymmetrical	Identical
Shape (eg. Rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Identical
Maximum Output Voltage (volts) (+/- %) at 500ohms, 2kohms and 10kohms	(+/- 10%) Positive: @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V Negative: @ 500ohms = 40V @ 2kohms = 40V @ 10kohms = 40V	(+/- 10%) Positive: @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V Negative: @ 500ohms = 40V @ 2kohms = 40V @ 10kohms = 40V	Identical
Maximum Output Current (specify	(+/- 10%) Positive:	(+/- 10%) Positive:	Identical

<table>
<tr><td>units) (+/- %) at 500 ohms, 2kohms and 10kohms</td><td>@ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA

Negative:
@ 500ohms = 5mA @ 2kohms = 5mA
@ 10kohms = 4mA</td><td>@ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA

Negative:
@ 500ohms = 5mA @ 2kohms = 5mA
@ 10kohms = 4mA</td><td></td></tr>
<tr><td>Pulse width (specify units)</td><td>Positive: 150-400 us
Negative: 600-1600 us</td><td>Positive: 150-400 us
Negative: 600-1600 us</td><td>Identical</td></tr>
<tr><td>Frequency (Hz)</td><td>1Hz or 40Hz</td><td>1Hz or 40Hz</td><td>Identical</td></tr>
<tr><td colspan="4">For multiphase waveforms only:</td></tr>
<tr><td>Symmetrical phases? (yes/no)</td><td>No</td><td>No</td><td>Identical</td></tr>
<tr><td>Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)</td><td>Positive: 150-400 us
Negative: 600-1600 us</td><td>Positive: 150-400 us
Negative: 600-1600 us</td><td>Identical</td></tr>
<tr><td>Net Charge (uC per pulse) (If zero, state method of achieving zero net charge)</td><td>1.85uC</td><td>1.85uC</td><td>Identical</td></tr>
<tr><td>Maximum Phase Charge (uC)</td><td>Positive: 9.02 uC
Negative: 8.86 uC</td><td>9.02µC</td><td>Equivalent</td></tr>
<tr><td>Maximum Current Density (RMS) (mA/cm2)</td><td>1.07 mA/cm2 (for 1 cm x 3 cm electrodes)</td><td><table><tr><th>Electrode Size:</th><th>Peak Current/ Imrs (Max):</th><th>Current Density</th></tr><tr><td>1 cm x 3 cm</td><td>20 mA /2.83 mA</td><td>0.93 mA/cm2</td></tr><tr><td>2.5 cm Ø</td><td>20 mA / 2.83 mA</td><td>0.57 mA/cm2</td></tr><tr><td>5 cm x 5 cm</td><td>20 mA / 2.83 mA</td><td>0.11 mA/cm2</td></tr><tr><td>9 cm x 5 cm</td><td>20 mA / 2.83 mA</td><td>0.06 mA/cm2</td></tr></table></td><td>Equivalent
Refer to Peak current value discussion below.</td></tr>
<tr><td>Maximum Power Density, (W/cm2), (using smallest electrode conductive surface area)</td><td>0.044W/cm2</td><td>0.044W/cm2</td><td>Identical</td></tr>
<tr><td>Burst Mode (ie. Pulse trains):</td><td>Not Applicable, No Burst Mode</td><td>Not Applicable, No Burst Mode</td><td>Identical</td></tr>
<tr><td>Pulses per burst</td><td>Not Applicable, No Burst Mode</td><td>Not Applicable, No Burst Mode</td><td>Identical</td></tr>
<tr><td>Bursts per second</td><td>Not Applicable, No Burst Mode</td><td>Not Applicable, No Burst Mode</td><td>Identical</td></tr>
<tr><td>Burst duration (seconds)</td><td>Not Applicable, No Burst Mode</td><td>Not Applicable, No Burst Mode</td><td>Identical</td></tr>
<tr><td>Duty Cycle: Line (b) x Line (c)</td><td>Not Applicable, No Burst Mode</td><td>Not Applicable, No Burst Mode</td><td>Identical</td></tr>
<tr><td>ON Time (seconds)</td><td>Not Fixed - User Controlled</td><td>Not Fixed - User Controlled</td><td>Identical</td></tr>
<tr><td>OFF Time (seconds)</td><td>Not Fixed - User Controlled</td><td>Not Fixed - User Controlled</td><td>Identical</td></tr>
</table>

Scapula anatomical site addition discussion:

The addition of the scapula protocols is essential for the optimization and achievement of the objectives of patients using MyndMove without departing from the existing anatomical sites already connected to the scapula, such as the posterior, anterior and middle deltoid muscles, which connect to the upper part of the scapula (Cleveland clinic, 2021), although the deltoids alone were not enough to achieve the movements intended by adding the scapula protocol (sideways reach, sideways reach with Scapula and hand opening, Forward reach with Scapula muscle , Forward reach with Scapula muscle + hand opening/closing, hand to mouth with Scapula muscle plus hand closing, and hand to mouth with Scapula muscle + hand closing). Scapula protocols were subject to planned validation testing on 3 healthy volunteers. The objective was to test each protocol on each subject to ensure that the induced motions achieve

the desired motions per the described use cases presented in section. Shoulder range of motion (flexion and abduction) under stimulation was collected using a goniometer.
Testing was performed at a clinical site called Lyndhurst and the Toronto Rehabilitation Institute of the University Health Network of the University of Toronto. All verification and validation was successfully performed per the design and development plans and under REB decision at the Toronto Rehabilitation Institute.
The addition of Scapula to the anatomical sites treated with MyndMove protocols fall within or at least are connected in movements of the same anatomical sites listed in the predicate device, the cleared MyndMove. In addition, these do not add new risk or change the existing risk profile.

References:
Cowan PT, Mudreac A, Varacallo M. Anatomy, Back, Scapula. [Updated 2021 Aug 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK531475/

Cleveland Clinic (2021). Deltoid Muscles. https://my.clevelandclinic.org/health/body/21875-deltoid-muscles.

Peak current value discussion.

The peak current for the cleared MyndMove is a function of electrode size, ranging from 5mA for a 3cm2 electrode. to the peak current 20mA for a 45cm2 electrode. For MyndMove 2.0 the peak current is also 20mA for all electrode sizes. The purpose of this change is to enable the therapist to select the peak currents to generate full muscle recruitment if using the smallest electrode size. This is particularly needed when stimulating denervated muscles. In all cases the peak current density does not exceed 2mA/cm2, the limit identified in IEC 60601-2-10, therefore the level of stimulation is considered safe. The risks of stimulation are described in the risk analysis and the benefit of treatment outweighs the risk.

Conclusion:

MyndMove 2.0 has the same indications for use and output characteristics as the predicate device MyndMove. MyndMove 2.0 is fundamentally an upgraded MyndMove enabled for home environment use as a prescription device. The differences in some specifications do not raise safety and effectiveness questions. The safety and effectiveness of adding scapula protocols to the anatomical sites was demonstrated through validation testing with healthy volunteers in a clinical setting, in addition to internal testing. The average current density regardless of electrode size does not incorporate risks or safety concerns; the smallest electrode surface area average current density it falls under the allowed 2mA/cm2 limit established by IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. Third party testing on the addition of features to meet home use requirements of 60601-1-11 concluded that MyndMove 2.0 is safe for home use within the same indications for use of the predicate device.

In conclusion, there are no fundamental differences between the MyndMove 2.0 and MyndMove device. The modifications made in MyndMove 2.0 did not raise different questions regarding safety and effectiveness. Both are prescription devices with the same indications for use and specifications except for slight technical differences. Therefore, the modified MyndMove 2.0 is deemed substantially equivalent to the predicate, the cleared MyndMove.