June 25, 2024

MyndTec Inc.
Yesmil Pena
Quality Assurance Manager
1900 Minnesota Court
Mississauga, Ontario L5N 3C9
Canada

Re: K233006
Trade/Device Name: MyndMove, MyndMove 2.0
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: May 31, 2024
Received: June 10, 2024

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

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

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

Sincerely,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices

OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233006

Device Name
MyndMove and MyndMove 2.0

Indications for Use *(Describe)*

MyndMove and MyndMove 2.0 are electrical stimulation devices indicated for the following uses:

Functional electrical stimulation (FES)

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) for general rehabilitation for:

- 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 and MyndMove 2.0 therapies can only be administered by Occupational or Physical Therapy professionals that have completed MyndMove training by MyndTec on the use of the MyndMove and MyndMove 2.0 Systems.

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 – K233006

Submitter / Owner Information

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

Contact Person

Yesmil Pena
Telephone: 905-363-0564 ext. 225
Toll Free: 1-888-363-0581
Fax: 1-877-796-4624
yesmil.pena@myndtec.com

Date Prepared:

June 21, 2024

Device Identification

A. Proprietary Name	MyndMove and MyndMove 2.0
B. Device Classification	Class II
C. Panel	Neurology
D. Device Product Code	GZI and IPF
E. Regulation	21 CFR 882.5810 (External functional neuromuscular stimulator) 21 CFR 890.5850 (Powered muscle stimulator)

Identification of Predicate Devices

Device	Applicant	510(k) No.	Date Cleared
MyndMove	MyndTec Inc.	K170564	August 30, 2017
MyndMove 2.0	MyndTec Inc.	K212149	March 03, 2022

Device Description

The subject devices of K233006 include MyndMove and MyndMove 2.0. There have been no changes to the technological characteristics of MyndMove or MyndMove 2.0 since the clearances of K170564 and K212149.

The MyndMove and MyndMove 2.0 Systems are neuromodulation devices that deliver short electrical pulses to stimulate muscle contractions and enhance motor recovery following Stroke or Spinal Cord Injury. The MyndMove and MyndMove 2.0 systems comprise the Stimulator device, stimulation electrodes and cables, hand and foot switches, and integrated software.

The Functional Electrical Stimulators in the MyndMove and MyndMove 2.0 are eight-channel devices

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/MyndMove 2.0 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/MyndMove 2.0 ecosystem including but not limited to patient unique IDs and prescriptions, therapist profiles and stimulation protocols.

MyndMove and MyndMove 2.0 Therapies 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/MyndMove 2.0 system.

MyndMove and MyndMove 2.0 use 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 and MyndMove 2.0 are 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 or MyndMove 2.0 protocols achieve a wide range of functions. During the delivery of MyndMove or MyndMove 2.0 therapy, the patient executes functional tasks with assistance from the therapist and the MyndMove/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 or 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 a movement. 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 and MyndMove 2.0 are electrical stimulation devices indicated for the following uses:

Functional electrical stimulation (FES)

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) for general rehabilitation for:

- 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 and MyndMove 2.0 therapies can only be administered by Occupational or Physical Therapy professionals that have completed MyndMove training by MyndTec on the use of the MyndMove and MyndMove 2.0 Systems.

Type of Use

Prescription Use (Rx)

Summary of Non-Clinical Testing

The subject devices conform to all applicable standards listed below, which were leveraged from the previously cleared predicate devices (K170564 and K212149). No additional non-clinical performance testing was conducted because there was no change to the hardware or software since clearances of MyndMove (K170564) and MyndMove 2.0 (K212149).

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.
13-79	IEC 62304:2006 Medical device software - Software life cycle processes.

The electrode cables included in the system comply with the U.S. Federal Performance Standard as set forth in 21 CFR 898 for electrode lead wires and Patient Cables. The patient contacting accessories included in the system (the electrodes and security tape) comply with the requirements for biocompatibility (ISO 10993-1).

Basis for Substantial Equivalence

There have been no changes made to the technological characteristics and therapy protocols of MyndMove or MyndMove 2.0 since their clearance in K170564 or K212149. Both MyndMove and MyndMove 2.0 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. MyndMove and MyndMove 2.0 devices of the present submission have identical technical specifications when compared to previously cleared MyndMove and MyndMove 2.0, as illustrated in the table below.

Substantial Equivalence Discussion for Subject Devices (MyndMove and MyndMove 2.0) and Primary Predicate Device (MyndMove, K170564) and Secondary Predicate Device (MyndMove 2.0, K212149)				
	Subject Devices (MyndMove and MyndMove 2.0)	**Primary Predicate Device (MyndMove)**	**Secondary Predicate Device (MyndMove 2.0)**	**SE Comparison**
510(k) Number	**K233006**	**K170564**	**K212149**	
Indications for Use	MyndMove and MyndMove 2.0 are electrical stimulation devices indicated for the following uses: Functional electrical stimulation (FES) 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) for general rehabilitation for: • 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 and MyndMove 2.0 therapies can only be administered by Occupational or Physical Therapy professionals that have completed MyndMove training by MyndTec on the use of the MyndMove and MyndMove 2.0 Systems.	MyndMove is an electrical stimulation device indicated for the following uses: Functional electrical stimulation (FES) 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.	MyndMove is an electrical stimulation device indicated for the following uses: Functional electrical stimulation (FES) 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.	Similar

Substantial Equivalence Discussion for Subject Devices (MyndMove and MyndMove 2.0) and Primary Predicate Device (MyndMove, K170564) and Secondary Predicate Device (MyndMove 2.0, K212149)				
	Subject Devices (MyndMove and MyndMove 2.0)	**Primary Predicate Device (MyndMove)**	**Secondary Predicate Device (MyndMove 2.0)**	**SE Comparison**
510(k) Number	**K233006**	**K170564**	**K212149**	
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 Serratus Anterior, Lower Trapezius, Upper Trapezius (Scapula)	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).	Identical
Where Used	MyndMove is intended to be used for therapy sessions in a clinical setting only MyndMove 2.0 is intended to be used for therapy sessions in a clinical setting and for home use by a qualified user.	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.	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the

Substantial Equivalence Discussion for Subject Devices (MyndMove and MyndMove 2.0) and Primary Predicate Device (MyndMove, K170564) and Secondary Predicate Device (MyndMove 2.0, K212149)				
	Subject Devices (MyndMove and MyndMove 2.0)	**Primary Predicate Device (MyndMove)**	**Secondary Predicate Device (MyndMove 2.0)**	**SE Comparison**
510(k) Number	**K233006**	**K170564**	**K212149**	
				MyndMove 2.0 cleared in K212149.
Regulated current or regulated voltage?	Current Regulated	Current Regulated	Current Regulated	Identical
Software/ firmware/ microprocessor or control? (yes/no)	Yes	Yes	Yes	Identical
Automatic overload trip? (yes/no)	Yes	Yes	Yes	Identical
Automatic no- load trip? (yes/no)	Yes	Yes	Yes	Identical
Automatic shut off? (yes/no)	Yes	Yes	Yes	Identical
User override control? (yes/no)	Yes	Yes	Yes	Identical
Indicator display:	Yes	Yes	Yes	Identical
– On/off status?	Yes	Yes	Yes	Identical

Substantial Equivalence Discussion for Subject Devices (MyndMove and MyndMove 2.0) and Primary Predicate Device (MyndMove, K170564) and Secondary Predicate Device (MyndMove 2.0, K212149)				
	Subject Devices (MyndMove and MyndMove 2.0)	**Primary Predicate Device (MyndMove)**	**Secondary Predicate Device (MyndMove 2.0)**	**SE Comparison**
510(k) Number	**K233006**	**K170564**	**K212149**	
(yes/no)				
– Low battery?(yes /no)	Yes	Yes	Yes	Identical
– Voltage/curr ent level? (yes/no)	Yes	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)	Stimulation time controlled by user. Max duration of stimulation program = 120 minutes (configurable in the backend)	Identical
Compliance with voluntary standards? (if yes, specify)	MyndMove: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 MyndMove 2.0 ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-2-10	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Compliance with 21 CFR 898? (yes/no)	Yes	Yes	Yes	Identical

Power Sources	MyndMove: Mains OR Rechargeable Li-Ion Battery. Rechargeable Li-Ion: 14.8 V DC, 2000 mAh Power Supply Input: 100-240 V AC, 1.2A, 5060 Hz Power Supply Output: 24 V DC, 4.16 A, 100W MyndMove 2.0: 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	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	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Method of line current isolation	Galvanic Isolation (transformer) 4000 VAC	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	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	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	Patient auxiliary current: Normal condition: < 100 uA Single fault condition: < 500 uA	Identical
Number of output odes (ie. Number of stimulation protocols)	MyndMove: Two Modes (applicable to all 33 stimulation protocols): Biphasic Symmetric Biphasic Asymmetric MyndMove 2,0: Biphasic Asymmetric	Two Modes (applicable to all 33 stimulation protocols): Biphasic Symmetric Biphasic Asymmetric	Biphasic Asymmetric	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0

				is identical to the MyndMove 2.0 cleared in K212149.
Number of output channels	8	8	8	Identical
Synchronous or alternating?	Asynchronous (channels are staggered)	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	Galvanic isolation (transformer): 1500VAC/3kV DC	Identical
Weight (lbs., oz.)	14lbs 6oz.	14lbs 6oz.	14lbs 6oz.	Identical
Dimensions (in.) [W x H x D] (including accessories)	MyndMove: Stimulator: 9.0 in x 4.3 in x 9.8 in MyndMove 2.0: Stimulator: L 33 cm x W 25 cm x H 13.5 cm	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	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
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	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	- 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 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 (e.g. Pulsed monophasic, biphasic)	MyndMove: Balanced Biphasic Symmetrical MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Balanced Biphasic Symmetrical	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Shape (eg. Rectangular, spike, rectified, sinusoidal)	MyndMove: Rectangular MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Rectangular	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in

				K212149.
Maximum Output Voltage (volts) (+/- %) at 500ohms, 2kohms and 10kohms	MyndMove: (+/- 10%) @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	(+/- 10%) @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.

Maximum Output Current (specify units) (+/- %) at 500 ohms, 2kohms and 10kohms	MyndMove: (+/- 10%) @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	(+/- 10%) @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Pulse width (specify units)	MyndMove: Positive: 150-400 us Negative: 150-400 us MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Positive: 150-400 us Negative: 150-400 us	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Frequency (Hz)	MyndMove: 1Hz or 40Hz MyndMove2.0: Not Applicable, No Symmetrical Output Mode	1Hz or 40Hz	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
For multiphase waveforms only:				
Symmetrical phases?	MyndMove: Yes	Yes	Not Applicable, No Symmetrical Output	The subject

(yes/no)	MyndMove 2.0: Not Applicable, No Symmetrical Output Mode		Mode	MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	MyndMove: Positive: 150-400 us Negative: 150-400 us MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Positive: 150-400 us Negative: 150-400 us	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Net Charge (uC per pulse) (If zero, state method of achieving zero net charge)	MyndMove: 2.00 uC MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	2.00 uC	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Maximum Phase Charge (uC)	MyndMove: 9.02 uC MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	9.02 uC	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in

				K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Maximum Current Density (RMS) (mA/cm2)	MyndMove: 1.36 mA/cm2 (for 1cm x 3cm electrode) MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	1.36 mA/cm2 (for 1cm x 3cm electrode)	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Maximum Power Density, (W/cm2), (using smallest electrode conductive surface area)	MyndMove: 0.044W/cm2 MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	0.044W/cm2	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Burst Mode (i.e., Pulse trains):	MyndMove: Not Applicable, No Burst Mode MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in

				K212149.
Pulses per burst	MyndMove: Not Applicable, No Burst Mode MyndMove2.0: Not Applicable, No Symmetrical Output Mode	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Bursts per second	MyndMove: Not Applicable, No Burst Mode MyndMove2.0: Not Applicable, No Symmetrical Output Mode	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Burst duration (seconds)	MyndMove: Not Applicable, No Burst Mode MyndMove2.0: Not Applicable, No Symmetrical Output Mode	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Duty Cycle:	MyndMove: Not Applicable, No Burst	Not Applicable, No Burst Mode	Not Applicable, No Symmetrical Output	The subject

Line **(b) x Line (c)**	Mode MyndMove2.0: Not Applicable, No Symmetrical Output Mode		Mode	MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
ON Time (seconds)	MyndMove: Not Fixed - User Controlled. MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Not Fixed - User Controlled	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
OFF Time (seconds)	MyndMove: Not Fixed - User Controlled MyndMove 2.0: Not Applicable, No Symmetrical Output Mode	Not Fixed - User Controlled	Not Applicable, No Symmetrical Output Mode	The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Biphasic Asymmetrical Output Mode				
Waveform (e.g. Pulsed monophasic, biphasic)	Balanced Biphasic Asymmetrical	Balanced Biphasic Asymmetrical	Balanced Biphasic Asymmetrical	Identical

Shape (e.g. Rectangular, spike, rectified sinusoidal)	Rectangular	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	(+/- 10%) Positive: @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V Negative: @ 500ohms = 40V @ 2kohms = 40V @ 10kohms = 40V	Identical
Maximum Output Current (specify units) (+/- %) at 500 ohms, 2kohms and 10kohms	(+/- 10%) Positive: @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA Negative: @ 500ohms = 5mA @ 2kohms = 5mA @ 10kohms = 4mA	(+/- 10%) Positive: @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA Negative: @ 500ohms = 5mA @ 2kohms = 5mA @ 10kohms = 4mA	(+/- 10%) Positive: @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA Negative: @ 500ohms = 5mA @ 2kohms = 5mA @ 10kohms = 4mA	Identical

<table>
<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>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>1Hz or 40Hz</td><td>Identical</td></tr>
<tr><td colspan="5">For multiphase waveforms only:</td></tr>
<tr><td>Symmetrical phases? (yes/no)</td><td>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>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>1.85uC</td><td>Identical</td></tr>
<tr><td>Maximum Phase Charge (uC)</td><td>MyndMove:
Positive: 9.02 uC
Negative: 8.86 uC
MyndMove 2.0: 9.02µC</td><td>Positive: 9.02 uC
Negative: 8.86 uC</td><td>9.02µC</td><td>The subject MyndMove is identical to the MyndMove cleared in K170564. The subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.</td></tr>
<tr><td>Maximum Current Density (RMS) (mA/cm2)</td><td>MyndMove:
1.07 mA/cm2 (for 1 cm x 3 cm electrodes)

MyndMove 2.0:</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 x3 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></table></td><td>The subject MyndMove is identical to the MyndMove cleared in K170564. The</td></tr>
</table>

	<table><tr><th>Electrode Size:</th><th>Peak Current/ Imrs (Max):</th><th>Current Density</th></tr><tr><td>1 cm x3 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>		<table><tr><td>9 cm x 5 cm</td><td>20 mA / 2.83 mA</td><td>0.06 mA/cm2</td></tr></table>	subject MyndMove 2.0 is identical to the MyndMove 2.0 cleared in K212149.
Maximum Power Density, (W/cm2), (using smallest electrode conductive surface area)	0.044W/cm2	0.044W/cm2	0.044W/cm2	Identical
Burst Mode (ie. Pulse trains):	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Identical
Pulses per burst	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Identical
Bursts per second	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Identical
Burst duration (seconds)	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Identical
Duty Cycle: Line (b) x Line (c)	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Not Applicable, No Burst Mode	Identical
ON Time (seconds)	Not Fixed - User Controlled	Not Fixed - User Controlled	Not Fixed - User Controlled	Identical
OFF Time (seconds)	Not Fixed - User Controlled	Not Fixed - User Controlled	Not Fixed - User Controlled	Identical

Conclusion:

MyndMove and MyndMove 2.0 included in the present submission have the same intended use, output characteristics, and therapy protocols as the predicate devices MyndMove (cleared under K170564) and MyndMove 2.0 (cleared under K212149). The indication for use statement is almost identical to what were cleared in 170564 and K212149 with the exception of a wording change in the Neuromuscular Electrical Stimulation (NMES) that is intended to provide an overall definition for the specific indications (i.e., NMES for general rehabilitation for: maintenance and/or increase of arm and hand range of motion, prevention or retardation of disuse atrophy, increase in local blood circulation, reduction of muscle spasm, re-education of muscles).

In conclusion, the subject MyndMove and MyndMove 2.0 devices are deemed substantially equivalent to the predicate MyndMove and MyndMove 2.0 devices.