DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 30, 2017

Myndtec Inc
Alexa Granger
Manager, Quality Assurance
2233 Argentia Road
Suite 307
Mississauga, L5N 2X7 CA

Re: K170564
Trade/Device Name: MyndMove System, MyndMove Functional Electrical Stimulator
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: July 28, 2017
Received: July 31, 2017

Dear Alexa Granger:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170564

Device Name
MyndMove System and MyndMove Functional Electrical Stimulator

Indications for Use *(Describe)*
MYNDMOVE is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES)
o 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)
o Maintenance and/or increase of arm and hand range of motion.
o Prevention and/or retardation of disuse atrophy.
o Increase in local blood circulation.
o Reduction of muscle spasm.
o 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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MyndTec

510(k) Summary

Submitter/Owner Information

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Contact Person

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Date Prepared

August 21, 2017

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
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	New Device

Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
NESS H200 Wireless Hand Rehabilitation System	Bioness Inc.	K123636	May 1, 2013

Device Description

The MyndMove 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 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 Therapy can only be administered by Trained MyndMove Therapists (TMMT) with assigned Therapist Log-In IDs. TMMTs are Occupational or Physical Therapists that have completed MyndMove training by MyndTec on the use of the MyndMove system.

MyndMove 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 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 protocols achieve a wide range of reaching and grasping functions. During the delivery of MyndMove therapy, the patient executes functional tasks with assistance from the therapist and the MyndMove device. The patient attempts to perform the movement and is then assisted to complete the movement when the therapist activates the MyndMove 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.

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Indications for Use

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 of muscle spasm.
  - 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.

There are three differences in the indications for use of the two devices.

The first difference is the addition of "arm and" before describing the treatment area. MyndMove can stimulate muscles in the whole arm, specifically, muscles of the pectoral girdle and shoulder, arm, forearm and hand complex. MyndMove stimulates 14 different muscles and muscle groups of the entire arm, whereas the NESS H200 Wireless is only stimulating muscles in the forearm and thumb (5 different muscle groups) treating only the hand. With 8 channels the MyndMove device can stimulate combinations of 3 to 8 of the 14 different muscles and muscle groups in one treatment protocol. As a result the MyndMove is able to deliver over 25 different reaching and grasping treatment protocols. The NESS H200 is limited to 3 channels and 5 electrodes due to the orthosis used to house the stimulation electrodes it can only stimulate the same 5 muscles groups, delivering two treatment protocols, namely palmar grasps and lateral pinch grasp.

The second difference in the indication is the specified spinal cord injury level of C3 to T1 for MyndMove, and only C5 for the NESS H200 Wireless. This change is similar to the first, as it relates to the area being treated. MyndMove treats areas of the arm that are both more proximal and more distal to the areas treated by the NESS H200 Wireless, as a result the spinal cord injury patient population that can benefit from MyndMove is larger.

Lastly, the NESS H200 Wireless includes an optional accessory the Intelli-Connect Earpiece triggering Device. This accessory is specified in the NESS H200 Wireless indications for use. MyndMove uses switches (hand or foot controlled) to trigger stimulation, the earpiece triggering device and statement in the NESS H200 Wireless indications for use is not applicable to MyndMove.

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Comparison of Technological Characteristics with the Predicate Device

The below Table 1 compares the technological characteristics of the NESS H200 Wireless and the MyndMove System.

Table 1: Characteristic Comparison of MyndMove ad NESS H200 Wireless

	MyndMove	***NESS H200 Wireless***	***Similar?***
K No.	***K170564***	***K123636***	
Indications for Use	MYNDMOVE is an electrical stimulation device indicated for the following uses: - Functional Electrical Stimulation (FES) o 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) o Maintenance and/or increase of arm and hand range of motion o Prevention and/or retardation of disuse atrophy o Increase in local blood circulation o Reduction of muscle spasm o 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.	The NESS H200 Wireless System is an electrical stimulation device indicated for the following uses: - Functional Electrical Stimulation (FES) o Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury. - NeuroMuscular Electrical Stimulation (NMES) o Maintenance and/or increase of arm and hand range of motion o Prevention and/or retardation of disuse atrophy o Increase in local blood circulation o Reduction of muscle spasm o Re-education of muscles The Intelli-Connect is an optional accessory device used exclusively with the H200 Wireless Orthosis through simple jaw movements.	Similar

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	MyndMove	NESS H200 Wireless	Similar?
K No.	K170564	K123636	
a. Basic Unit Characteristics			
i. 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	Controller: Rechargeable AAA NiMH 1.2V, 900-1100 mAh Orthosis: Rechargeable Li-Ion 3.7 V, 280-350 mAh Charger Power Supply Input: 100-240 V AC, 400mA, 50-60 Hz Charger Power Supply Output: 5V +/- 5%, 2400 mA	Different
- Method of line current isolation	Galvanic Isolation (transformer) 4000 VAC	Not Applicable – Battery Operated	Different
Patient Leakage Current:			
a) Normal condition (uA)	Earth Leakage: < 500 uA Lead to Ground: < 100 uA	Not Available in 510k	Not Known
b) Single fault condition (uA)	Earth Leakage: < 1000 uA Lead to Ground: < 500 uA Patient on Mains: < 5000 uA	Not Available in 510k	Not Known
ii. 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	Not Available in 510k	Not Known
iii. Number of output modes (ie. Number of stimulation protocols)	Two Modes (applicable to all 33 stimulation protocols): - Biphasic Symmetric - Biphasic Asymmetric	One Mode (applicable to all 7 stimulation protocols): - Biphasic Symmetric	Similar
iv. Number of output channels	8	3	Different
- Synchronous or Alternating?	Asynchronous (channels are staggered)	Not Available in 510k	Not Known
- Method of channel isolation	Galvanic isolation (transformer): 1500VAC/3kV DC	Not Available in 510k	Not Known
v. Regulated current or regulated voltage?	Current Regulated	Not Available in 510k	Not Known
vi. Software/ firmware/ microprocessor control? (yes/no)	Yes	Yes	Same

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	MyndMove	NESS H200 Wireless	Similar?
K No.	K170564	K123636	
vii. Automatic overload trip? (yes/no)	Yes	Yes	Same
viii. Automatic no-load trip? (yes/no)	Yes	Yes	Same
ix. Automatic shut off? (yes/no)	Yes	Yes	Same
x. User override control? (yes/no)	Yes	Yes	Same
xi. Indicator display:	Yes	Yes	Same
- On/off status? (yes/no)	Yes	Yes	Same
- Low battery? (yes/no)	Yes	Yes	Same
- Voltage/current level? (yes/no)	Yes	Yes	Same
xii. Timer range (minutes)	Stimulation time controlled by user. Max duration of stimulation program = 120 minutes (configurable in the backend)	Max duration of stimulation program = 245 minutes	Similar
xiii. Compliance with voluntary standards? (if yes, specify)	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2	Similar
xiv. Compliance with 21 CFR 898? (yes/no)	Yes	Not Available in 510k	Same
xv. Weight (lbs., oz.)	14lbs 6oz.	Controller: 1.5 oz. Orthosis: 10.6 oz.	Different
xvi. Dimensions (in.) [W x H x D] (including accessories)	Stimulator: 9.0 in x 4.3 in x 9.8 in	Controller Dimensions: 1.8 in x 0.7 in x 2.9 in Orthosis (Small): 4.33 in x 10.63 in x 3.54 in Orthosis (Medium): 4.33 in x 10.63 in x 3.54 in Orthosis (Large): 5.11 in x 11.81 in x 5.11 in	Different

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	MyndMove	NESS H200 Wireless	Similar?
K No.	K170564	K123636	
xvii. Housing materials and construction (including accessories)	Stimulator Housing Materials: - Enclosure = Lexan PCB HPX4R - Plastic Bezel = ABS Plastic - Rubber Membrane = Silicone	Orthotic Materials: - Main body = Rislan BZM 30 OTL - Wing Cover = TEREZ ABS 5010 - Wrist Insert = flexible foam, two components urethane nonintegral skin, Purtec GMBH - Thenar = Dow Corning Silicone Rubber NPC 40	Different
xv. Additional Features (specify, if applicable)	- Timing of stimulation controlled by user (therapist) through the use of a hand or foot switch	- Orthotic - Controller - Intelli-Connect Earpiece Trigger Device	Different
xvi. Clinical and Human Factors Characteristics:			
a) Target Population	- Patients with hemiplegia due to stroke or upper limb paralysis due to C3-T1 spinal cord injury.	- Patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.	Similar
b) Anatomical Site	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 NESS H200 Wireless stimulates the following muscles: - Extensor Digitorum, Extensor Pollicis Brevis and Longus - Thenar Muscle Group - Flexor Digitorum Superficialis, Flexor Pollicis Longus	Similar
c) Where Used	- Used for therapy sessions in a clinical setting only.	- Used both for therapy session in a clinical setting and for patient to take home.	Similar

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	MyndMove	NESS H200 Wireless	Similar?
K No.	K170564	K123636	
d) 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.	- Orthotic with electrical stimulation. - Reusable Cloth Electrodes - 3 stimulation channels, up to 5 electrodes. - Controlled by a wireless control unit. - Orthotic must be fitted by clinician for each patient. - Must be programmed by Clinical using the HP iPAQ Clinician Programmer. - Used by Clinician and Patient.	Different
b. Output specifications for each output mode (ie. Stimulation protocol)			
Biphasic Symmetrical Output Mode			
i. Waveform (eg. Pulsed monophasic, biphasic)	Balanced Biphasic Symmetrical	Balanced Biphasic Symmetrical	Same
ii. Shape (eg. Rectangular, spike, rectified sinusoidal)	Rectangular	Not Available in 510k	Not Known
iii. Maximum Output Voltage (volts) (+/- ___%) at 500ohms, 2kohms and 10kohms	(+/- 10%) @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V	120V Resistance and accuracy for maximum output voltage not available in 510k.	Different
iv. Maximum Output Current (specify units) (+/- ___%) at 500 ohms, 2kohms and 10kohms	(+/- 10%) @ 500ohms = 20mA @ 2kohms = 20mA @ 10kohms = 16mA	80mA Maximum Current Intensity by electrode: Electrodes 1, 2, 3 and 5 = 13.1mA rms Electrode 4 = 18.6ma rms Resistance and accuracy for maximum output current not available in 510k.	Different

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	MyndMove	***NESS H200 Wireless***	***Similar?***
K No.	***K170564***	***K123636***	
v. Pulse width (specify units)	Positive: 150-400 us Negative: 150-400 us	Positive: 100, 200, 300 us Negative: 100, 200, 300 us Interphase period: 50us Max Total Pulse Duration: 250, 450, 650 us	Similar
vi. Frequency (Hz)	1Hz or 40Hz	20-45Hz, 5 Hz Resolution	Similar
vii. For multiphase waveforms only:			
- Symmetrical phases? (yes/no)	Yes	Yes	Same
- Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	Positive: 150-400 us Negative: 150-400 us	250, 450, 650 us	Different
viii. Net Charge (uC per pulse) (If zero, state method of achieving zero net charge)	2.00 uC	Not Available in 510k	Not Known
ix. Maximum Phase Charge (uC)	9.02 uC	Not Available in 510k	Not Known
x. Maximum Current Density (RMS) (mA/cm2)	1.36 mA/cm2 (for 1cm x 3cm electrode)	Not Available in 510k	Not Known
xi. Maximum Power Density, (W/cm2), (using smallest electrode conductive surface area)	0.044W/cm2	Not Available in 510k	Not Known
xii. Burst Mode (ie. Pulse trains):	Not Applicable, No Burst Mode	Details Not Available in 510k	Different
- Pulses per burst	Not Applicable, No Burst Mode	Details Not Available in 510k	Different
- Bursts per second	Not Applicable, No Burst Mode	Details Not Available in 510k	Different
- Burst duration (seconds)	Not Applicable, No Burst Mode	Details Not Available in 510k	Different
- Duty Cycle: Line (b) x Line (c)	Not Applicable, No Burst Mode	Details Not Available in 510k	Different
xiii. ON Time (seconds)	Not Fixed - User Controlled	Not Available in 510k	Not Known
xiv. OFF Time (seconds)	Not Fixed - User Controlled	Not Available in 510k	Not Known
Biphasic Asymmetrical Output Mode			
i. Waveform (eg. Pulsed monophasic, biphasic)	Balanced Biphasic Asymmetrical	Not Applicable, Biphasic Symmetrical Mode Only	Different

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	MyndMove	NESS H200 Wireless	Similar?
K No.	K170564	K123636	
ii. Shape (eg. Rectangular, spike, rectified sinusoidal)	Rectangular	Not Applicable, Biphasic Symmetrical Mode Only	Different
iii. Maximum Output Voltage (volts) (+/- ___%) at 500ohms, 2kohms and 10kohms	(+/- 10%) Positive: @ 500ohms = 160V @ 2kohms = 160V @ 10kohms = 160V Negative: @ 500ohms = 40V @ 2kohms = 40V @ 10kohms = 40V	Not Applicable, Biphasic Symmetrical Mode Only	Different
iv. 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	Not Applicable, Biphasic Symmetrical Mode Only	Different
v. Pulse width (specify units)	Positive: 150-400 us Negative: 600-1600 us	Not Applicable, Biphasic Symmetrical Mode Only	Different
vi. Frequency (Hz)	1Hz or 40Hz	Not Applicable, Biphasic Symmetrical Mode Only	Different
vii. For multiphase waveforms only:			
- Symmetrical phases? (yes/no)	No	Not Applicable, Biphasic Symmetrical Mode Only	Different
- Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	Positive: 150-400 us Negative: 600-1600 us	Not Applicable, Biphasic Symmetrical Mode Only	Different
viii. Net Charge (uC per pulse) (If zero, state method of achieving zero net charge)	1.85uC	Not Applicable, Biphasic Symmetrical Mode Only	Different
ix. Maximum Phase Charge (uC)	Positive: 9.02 uC Negative: 8.86 uC	Not Applicable, Biphasic Symmetrical Mode Only	Different
x. Maximum Current Density (RMS) (mA/cm2)	1.07 mA/cm2 (for 1 cm x 3 cm electrodes)	Not Applicable, Biphasic Symmetrical Mode Only	Different

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	MyndMove	NESS H200 Wireless	Similar?
K No.	K170564	K123636	
xi. Maximum Power Density, (W/cm2), (using smallest electrode conductive surface area)	0.044W/cm2	Not Applicable, Biphasic Symmetrical Mode Only	Different
xii. Burst Mode (ie. Pulse trains):	Not Applicable, No Burst Mode	Not Applicable, Biphasic Symmetrical Mode Only	Different
- Pulses per burst	Not Applicable, No Burst Mode	Not Applicable, Biphasic Symmetrical Mode Only	Different
- Bursts per second	Not Applicable, No Burst Mode	Not Applicable, Biphasic Symmetrical Mode Only	Different
- Burst duration (seconds)	Not Applicable, No Burst Mode	Not Applicable, Biphasic Symmetrical Mode Only	Different
- Duty Cycle: Line (b) x Line (c)	Not Applicable, No Burst Mode	Not Applicable, Biphasic Symmetrical Mode Only	Different
xiii. ON Time (seconds)	Not Fixed - User Controlled	Not Applicable, Biphasic Symmetrical Mode Only	Different
xiv. OFF Time (seconds)	Not Fixed - User Controlled	Not Applicable, Biphasic Symmetrical Mode Only	Different

The MyndMove System is intended to be used by battery or mains power, the NESS H200 Wireless is designed to be used by battery power only. As a result, the power sources for the two devices are not the same and line current isolation is not applicable for the NESS H200 device. The MyndMove system requires a larger battery compared to the NESS H200 device due to the increased number of channels and the built-in touch screen user interface.

The MyndMove System and the NESS H200 Wireless differ in the number of output channels each device has. The NESS H200 Wireless has 3 channels, where as the MyndMove System has 8. The increased number of channels the MyndMove System has compared to the NESS H200 Wireless allows for stimulation of more muscles groups.

The maximum duration of stimulation for the two devices is also different, the NESS H200 has a maximum of 245 minutes whereas the MyndMove System's maximum is 120 minutes, within the range of the predicate's maximum.

The NESS H200 Wireless has one mode, Biphasic Symmetric. The MyndMove System has two modes a Biphasic Symmetric Mode, similar to the NESS H200, and a Biphasic Asymmetric mode.

When comparing the Symmetric modes of the two devices the maximum output voltage of the MyndMove System is higher than the NESS H200 but the maximum current output is lower and within range. The maximum output of the NESS H200 Wireless at 500 ohms, 2 kohms and 10 kohms is not provided in the 510k and a more detailed comparison cannot be completed. The pulse width of the output mode for both positive and negative pulses for the two devices are substantially equivalent, the NESS H200 is between 100 and 300 us and the MyndMove System is between 150 to 400 us, the MyndMove pulse width is within range of other legally marketed NMES devices (for example K153696 has a pulse width of 300 to 400 us). The output

frequency of the MyndMove system of 1-40 Hz is substantially equivalent to the NESS H200 Wireless output frequency.

The MyndMove System is compliant with requirements of IEC 60601-1, 60601-1-2 and 60601-2-10. Though there are differences for some of the technical and output characteristics of MyndMove compared to the NESS H200 Wireless no new questions of safety are raised by these differences.

Differences between the NESS H200 Wireless and the MyndMove System lie in the physical design of the two medical devices. The NESS H200 Wireless is an orthosis with built in electrodes and the MyndMove System is a Stimulator Unit with a built-in touch screen user interface that connects to electrodes by use of traditional cables. As a result, the weight, dimensions and power requirements for the two devices are different. These differences do not raise new questions of safety or effectiveness of the MyndMove System.

The difference in design of the two devices does not adversely affect safety and effectiveness of the MyndMove System. The MyndMove System is substantially equivalent to the NESS H200 Wireless predicate device.

Summary of Non-Clinical Testing

The MyndMove System has been evaluated for electrical safety and has been found to conform with applicable medical device safety standards. The MyndMove System successfully passed all testing in accordance with the defined requirements and the following ***international standards***:

FDA Standards Database No.	***Standard Title***	***Version***
17-11	IEC 60601-2-10 Medical Electrical Equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	2.0
19-4	ANSI/AAMI ES60601-1:2005/A1:2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).	3.0
5-89	IEC 60601-1-6:2010 A1-2015 Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.	3.1
13-32	62304:2006 Medical device software - software life cycle processes.	1.0
5-114	IEC 62366-1 Edition 1.0 2015-02, medical devices - part 1: application of usability engineering to medical devices [including corrigendum 1 (2016)]	1.0

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19-2	AAMI/ANSI/IEC 60601-1-2:2007/(R) 2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)	3.0

Testing was completed in accordance with FDA's guidance/draft guidance listed below:

- Guidance for Industry, FDA Reviewers/Staff and Compliance - Guidance Document for Powered Muscle Stimulator 510(k)s issued on June 9, 1999
- Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices issued on February 3, 2016
- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005
- Guidance for Industry and FDA Staff - Radio Frequency Wireless Technology in Medical Devices issued on August 14, 2013

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***).

Summary of Clinical Testing

This submission referenced the following clinical studies in both stroke and spinal cord injured populations using FES therapy:

- Popovic MR et al. Functional electrical therapy: Retraining grasping in spinal cord injury, Spinal Cord, 2006;44(3):143-151.
- Popovic MR et al. Neuroprosthesis for restoring reaching and grasping functions in severe hemiplegic patients Neuromodulation 2005;8(1):60-74.
- Thrasher TA, Zivanovic V, McIlroy W, et al. Rehabilitation of reaching and grasping function in severe hemiplegic patients using functional electrical stimulation therapy. Neurorehabil Neural Repair.2008;22(6):706–14.
- Popovic MR, Kapadia N, Zivanovic V, et al. Functional electrical stimulation therapy of voluntary grasping versus only conventional Rehabilitation for patients with subacute incomplete tetraplegia: a randomized clinical trial. Neurorehabil Neural Repair. 2011.
- Desai N. et al. Influence of different rehabilitation therapy models on patient outcomes: Hand function therapy in individuals with incomplete SCI. Journal of Spinal Cord Medicine, 2014;37(6):734-743.

The MyndMove System incorporates the stimulation protocols used in the FES therapy for the above mentioned clinical studies and couples it with new hardware and software. The stimulation protocols with the MyndMove System are substantially equivalent to the protocols delivered in the studies completed with a Compex electrical stimulation device. The below Table 2 summarizes the Clinical experience with the MyndMove System.

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Table 2: Summary of Clinical Experience with MyndMove

Study	***Study Summary***
MyndMove Therapy for Severe Hemiparesis of the Upper Limb Following Stroke	Open label clinical study on people with stroke and low levels of arm and hand function as characterized by Chedoke–McMaster Stages of Motor Recovery 1 and 2, and Upper Extremity Fugl-Meyer Score (UE-FM) of ≤ 19. This ongoing study is designed to investigate the efficacy of 20 one-hour sessions of MyndMove therapy in 3 cohorts of participants: (1) early sub-acute (< 2 months), (2) late sub-acute (2 - 6 months) and (3) chronic (> 6 months) periods of recovery. Recruitment of 25 participants within each cohort is planned. The enrolment of the chronic cohort is complete and the results were reported by Hebert *et al* [1]. Twenty-four of 25 individuals completed 19 of 20 sessions. One study participant was withdrawn from the study for medical reasons unrelated to MyndMove therapy. After only twenty (20) 1-hour sessions of MyndMove therapy, 14 out of 24 (58%) people with chronic stroke realized clinically meaningful improvements in upper extremity voluntary mobility as measured by a gain in UE-FM of more than 5 points
Lead-In Usability Evaluation of MyndMove Prototype *November 20, 2013*	Lead-In Usability Testing was also completed on an early prototype version of MyndMove. The Lead-In Testing evaluated the use of the MyndMove System with 5 end user volunteers administering treatment to 5 healthy volunteers. End User Participants received three hours of training on the use of the device before the evaluation portion.
MyndMove Human Factors Formative Evaluation *April 4, 2014*	A second round of Usability Testing with 5 end user-healthy volunteer pairs. End User Participants received three hours of training on the use of the device before the evaluation portion.
MyndMove Human Factors Validation Testing *February 24, 2017*	The validation testing using simulated-use scenarios where 15 end user participants delivered therapy to 15 health volunteer participants. The testing sessions consisted of participant orientation, eight use scenarios corresponding to tasks that are critical to the safe and effective device use, and debrief interviews. After completing the scenarios, participants were asked to provide subjective feedback regarding any usability issues they encountered. Each end user was trained on the use of MyndMove before the start of the testing session.

Conclusion

The MyndMove System is substantially equivalent to the NESS H200 Wireless because it has the same intended use as the predicate device. Non-Clinical and Clinical testing data supports that the MyndMove System is as safe and effective as the NESS H200 Wireless.

[1] Hebert et al. Can severe upper extremity hemiplegia improve with functional electrical stimulation? Ontario Society of Occupational Therapists Conference, Kingston, Canada Sept 26, 2015.

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