November 6, 2025

Motive Health Inc.
℅ Prithul Bom
Most Responsible Party
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K253478
Trade/Device Name: Motive™ Muscle Stimulator for Lower Back (OT01-1003)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 10, 2025
Received: October 14, 2025

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tushar Bansal -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253478

Please provide the device trade name(s).

Motive™ Muscle Stimulator for Lower Back (OT01-1003)

Please provide your Indications for Use below.

The Motive™ Muscle Stimulator for Lower Back is intended for the stimulation of healthy muscles to improve or facilitate muscle performance.

The Motive™ Muscle Stimulator for Lower Back is not intended to be used in conjunction with therapy or treat diseases or medical conditions of any kind.

The Motive™ Muscle Stimulator for Lower Back device is indicated for adults of 22 years of age and older.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary
Motive™ Muscle Stimulator for Lower Back
Motive Health, Inc.

1 Regulatory Information

1.1	**Trade/Proprietary Name:**	**Motive™ Muscle Stimulator for Lower Back**
1.2	**Common Name:**	**Powered muscle stimulator**
1.3	**Regulation Names & Numbers:**	**Powered muscle stimulator**, 21 CFR 890.5850 **Product Codes:** **Code- NGX**; Powered muscle stimulator
1.4	**Classification:**	**Powered muscle stimulator**: II
1.5	**Manufacturer Name:**	Motive Health, Inc. 2120 East 6th Street, Suite 8 Tempe, AZ 85281 Telephone (480) 239-8553 FAX (866) 296-2772

These devices are reviewed by the Division of Neurological and Physical Medicine Devices.

2 Submission Information

Submission Number:	K253478
Date:	October 14, 2025
Contact:	Pete Kilpatrick 2120 East 6th Street, Suite 8 Tempe, AZ 85281 pkilpatrick@mymotive.com Telephone (480) 239-8553 FAX (866) 296-2772

3 Indications for Use

The Motive™ Muscle Stimulator for Lower Back is intended for the stimulation of healthy muscles to improve or facilitate muscle performance.

The Motive™ Muscle Stimulator for Lower Back is not intended to be used in conjunction with therapy or treat diseases or medical conditions of any kind.

The Motive™ Muscle Stimulator for Lower Back device is indicated for adults of 22 years of age and older.

4 Device Description

The Motive™ Muscle Stimulator for Lower Back is an over-the-counter electrical muscle stimulator (or Neuromuscular Electrical Stimulation (NMES) therapy) used to stimulate healthy muscles to improve or facilitate muscle performance. The Motive Muscle Stimulator for Lower Back applies an electrical current through a power regulated output NMES system to strengthen muscles through repeated contractions. The device is placed over the applicable muscle groups to deliver NMES treatment to the user.

4.1 Electrical Muscle Stimulator (NMES therapy)

The Motive™ Muscle Stimulator for Lower Back (subject device) and the Motive™ Knee Wrap (reference device, K220738) utilize the same Controller and deliver an identical neuromuscular electrical stimulation (NMES) waveform, protocol, and pulse amplitude to strengthen muscles. The device uses a patented waveform, delivered through a power-regulated output and a closed-loop feedback NMES system, to stimulate healthy muscles and enhance muscle performance through repeated contractions. The waveform is generated by a pulse generator (Controller) and delivered non-invasively via electrodes placed on the skin. The patented waveform in the subject Motive™ Muscle Stimulator for Lower Back device is identical to the reference Motive™ Knee Wrap device. The NMES waveform information and rated outputs for both subject and reference devices are identical.

4.2 Mobile Application (App)

The electrical stimulation therapy is initiated and managed wirelessly by the User using the MyMotive™ App which is developed for use on smart devices that interact with the system's Controller.

4.3. Lower Back Electrodes / Therapy Pad

The Motive™ Muscle Stimulator for Lower Back (subject device) includes a custom-designed lower back therapy pad with three (3) cutaneous electrodes. This pad is made from the identical raw materials as the reference device's knee therapy pad (Motive Knee Wrap), differing only in its geometry. Like the Motive Knee Wrap, the Motive™ Muscle Stimulator for Lower Back therapy pad is supplied non-sterile, intended for single-patient use with multiple applications, and is disposable. During treatment, the pad is placed on the lower back and gluteus medius to deliver electrical stimulation when connected to the Controller.

4.4 Conductive Gel

The Conductive Gel is a salt-free, chloride-free gel designed for electromedical procedures such as NMES and TENS.

4.5 Wireless Communications

The Motive™ Muscle Stimulator for Lower Back device incorporates a Bluetooth Low Energy (BLE) connection module for wireless communication, allowing it to pair with a Bluetooth-enabled mobile device running the mobile application, available on App stores. The App provides a virtual control panel with on-screen buttons for user operation.

The Controller is connected to the Lower Back Electrodes / Therapy Pad through a proprietary interface featuring a keyed design with a magnetic force to ensure connection to the Controller's pogo pins. The Controller serves as the primary safety, ensuring stimulation output never exceeds IEC 60601-2-10 limits. The mobile application allows the user to adjust the treatment level to achieve comfortable muscle contractions. If the Bluetooth connection is lost, the Controller pauses treatment, and the mobile application alerts the user to check the device.

The Controller includes an LED indicator to display status relating to battery charge, stimulation, and Bluetooth activity. The Controller is powered by an internal 3.7V Li-Po rechargeable battery, which can be recharged via the USB-C port using the provided cable.

4.6 Software

The subject Motive Muscle Stimulator for Lower Back operates using embedded Controller firmware, a mobile App, and Web Services software. The Controller's embedded firmware is a core component that manages the selection, adjustment, and delivery of the treatment program. It runs on the Controller, interfacing with the stimulation pulse generator and the mobile application.

Available for free download from app stores (iOS and Android), the mobile application operates on a mobile platform and communicates with the Controller via a Bluetooth Low Energy (BLE) connection. It provides an intuitive interface for users to control the neuromuscular electrical stimulation (NMES) therapy, allowing them to select, administer, and adjust therapy intensities while managing health and wellness related to their treatment.

4.7 Controller and the App

The Controller's primary function is to generate neuromuscular electrical stimulation (NMES) therapy and transmit therapy metrics to the mobile App. Once the mobile application is installed and a wireless connection is established between the Controller and the user's mobile device, the user can access all device features.

The mobile application, downloaded from app stores (iOS or Android), provides an intuitive and interactive graphical user interface that manages interactions between the Controller and the user. Its design emphasizes user engagement and therapy compliance as key features. Help and informational screens are integrated throughout the App, appearing on specific screens to guide users about features or conditions.

Upon downloading the App, users are guided through a series of chronological screens to perform the following tasks such as setting up the device, selecting therapy options, and monitoring treatment progress:

- New user onboarding
- Review and acceptance of Product Warnings
- Reading and accepting the mobile application Terms of Use and Conditions
- Creating a user profile
- Pairing the App with the Controller
- Registering a therapy pad
- Device setup (therapy pad and controller placement over the applicable muscle group)
- Starting the treatment
- Managing the treatment

4.8 Web Services (API, Database)

The Motive™ Web Services, a Medical Device Data System (MDDS), enables the electronic transfer, storage, retrieval, and display of data from the user's App and Controller. It features an encrypted database hosted on secure cloud-based servers and an Application Programming Interface (API) that allows the mobile application to send, receive, read, or write data to the database and perform logic tasks. Web Services ensures persistent storage and retrieval of collected data.

5 General Electrical Muscle Stimulation Device Features and Output Characteristics

The following two Tables represent the Motive device electrical stimulation features and the neuromuscular electrical stimulation (NMES) therapy output specifications.

Table 1 - Motive™ Muscle Stimulator for Lower Back general electrical stimulation features

No. of Output Modes	1
No. of Output Channels	2
Regulated Current, Voltage, or Power	Regulated Power
Software/Firmware/Microprocessor Control?	Yes
Automatic shut off?	Yes
Patient device control?	Yes
Indicator display- Low Battery?	Yes
Indicator display- Voltage/Current Level?	Yes
Timer range (minutes)	20 minutes

Table 2 - Motive™ Muscle Stimulator for Lower Back therapy program output specifications

Waveform	Pulsed Monophasic
Shape	Complex
Pulse width	5 ms
Frequency	50 pps
Maximum current density @ 500Ω	0.72 mA/cm^2 (rms)
Maximum power density (using smallest electrode conductive surface area) @ 500Ω	0.007 W/cm^2
Maximum phase charge @ 500Ω	373.9 µC
Maximum output voltage (V_{RMS}) (±10%) @ 500Ω	9.4 V

Maximum output current (I_{RMS}) (±10%) @ 500Ω	18.7 mA
Power source	Li-Polymer Battery 500mAh 3.7 VDC
Contraction time	1.0 s
Relaxation time	1.4 s
Treatment session	20 minutes

6 NMES Waveform

The NMES treatment program pulse parameters are defined below in Table 3.

Table 3 - Motive™ Muscle Stimulator for Lower Back NMES waveform pulse parameters

Pulse shape	Complex	
Treatment duration	20 minutes	
Frequency	50 pps	
Pulse width	5 ms	
Duty cycle	25%	
Work cycle	12 s	
Relaxation time	10 s	
Contraction time	5 cycles	1 s
Rest time		1.4 s

In the treatment program, the work cycle consists of the combination of five cycles of contraction and rest. Contraction time is the actual stimulation contraction period. Rest time is the period between contractions to wait to oscillate the stimulation between the two channels. Relaxation time is a period of no stimulation between the work cycles.

7 Recommended Usage

Motive™ Muscle Stimulator for Lower Back is recommended to be used daily. Each session of therapy is 20 minutes in length.

8 Summary of Non-Clinical/ Bench Studies

To demonstrate the safety, the Motive™ Muscle Stimulator for Lower Back device was tested for electrical safety, electromagnetic compatibility, usability, biocompatibility, and risk management requirements per the following standards:

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, 3rd Edition, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014/AMD1:2020, 4th Edition, Medical Electrical Equipment- Part 1-2: General requirements for basic safety and essential performance —Collateral standard: Electromagnetic compatibility — Requirements and tests
- IEC 60601-2-10:2012/AMD1:2016/AMD2:2023, 2nd Edition, Medical Electrical

Equipment- Part 2-10: Particular Requirements for the Safety of Nerve and Muscle Stimulators

- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, 2nd Edition, Medical Electrical Equipment- Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

- IEC 62133-2:2027/AMD1:2021, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

- IEC 62366-1:2015/AMD1:2020, Medical devices – Part 1: Application of usability engineering to medical devices

- Federal Register CFR 47, Part 15, subpart B, Radiated Emissions (Part 15.109(a), Class B), Conducted Emissions (Part 15.107(a), Class B)

- AIM 7351731 Rev 3.00 (2021-06-04) – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

- IEEE/ANSI C63.27-2021 – American National Standard for Evaluation of Wireless Coexistence

- AAMI TIR69 2017(R2020) **-** Risk management of radio-frequency wireless coexistence for medical devices and systems

- ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization

- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

9 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Motive™ Muscle Stimulator for Lower Back device and complies with the IEC 60601-1, IEC 60601-2-10, and 60601-11 standards for safety and the IEC 60601-1-2 standard for EMC.

10 Software Verification & Validation Testing

The Motive™ Muscle Stimulator for Lower Back device software has been validated in accordance with the requirements set forth in the following guidance documents:

- FDA Guidance Document, Guidance for the Content of Premarket Submission for Device Software Functions, June 14, 2023
- FDA Guidance Document - Policy for Device Software Functions and Mobile Medical

510(k)

Applications, September 29, 2022

- FDA Guidance Document, Off-The-Shelf Software Use in Medical Devices, August 11, 2023

The software validation tests demonstrated that the software version meets its design requirements.

11 Cybersecurity Controls

Cybersecurity information and supporting documents have been created and submitted according to the requirements set forth in the following guidance document:

- FDA guidance document, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, 2025

Cybersecurity-related activities included system assessment and mitigations of vulnerabilities of the Motive™ Muscle Stimulator for Lower Back device. Details related to system design features, processes, testing, and controls to manage and mitigate risk are included in this submission.

12 Human Factors and Usability

A self-selection study and human factors study including usability assessment was conducted to validate the usability of the Motive™ Muscle Stimulator for Lower Back device as an over-the-counter device and for home use. The results of the study support the labeling content and User's Manual instructions for successfully using the device as intended. The results of the human factors and usability study substantiate the acceptability of the risks identified during the risk assessment activities.

The human factors validation study usability testing was conducted in accordance with the following regulatory documents:

- FDA Guidance – Applying Human Factors and Usability Engineering to Medical Devices (2016)
- FDA Draft Guidance – Content of Human Factors Information in Medical Device Marketing Submissions (2022)
- IEC 62366-1:2015+A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices

13 Biocompatibility / Material

The patient contacting materials used in the Motive™ Muscle Stimulator for Lower Back device components include the therapy pad and conductive gel. The biocompatibility of the therapy pad was cleared under 510(k) submission K230533. The biocompatibility testing had been conducted according to the requirements of ISO 10993:2009 and tested as a surface contacting/skin contact/ >24 hour to 30 days prolonged exposure. Refer to Section 8. Summary of Non-Clinical / Bench Studies for standard compliance.

The conductive gel complies with ISO 10993-1:2009 biocompatibility standards and is a pre-amendment device, exempt from 510(k) requirements as it was legally marketed before May 28, 1976.

From the evaluation and submitted information, the components of the Motive™ Muscle Stimulator for Lower Back device were found to be biocompatible for its use.

14 Shelf life/ Sterility

The non-invasive nature of the device obviates the need for sterile components; however, patient-contacting surfaces should be capable of being cleaned as needed. The Motive™ Muscle Stimulator for Lower Back device is provided for single person use and does not require any of the components to be sterilized by the end user. It is intended for external use only. The therapy pad is disposable and can be replaced as needed.

15 Performance Testing- Bench Testing of Electrical Muscle Stimulation (NMES) Waveform

All features and output specifications of the device, including those identified in Tables 1 and 2, were verified by individual pulse output waveform tracings for loads of 500Ω, 2kΩ, and 10kΩ to simulate conditions that the Motive™ Muscle Stimulator for Lower Back device could encounter during use.

16 Comparison of Technological Characteristics with the Predicate Device

Motive Health, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Motive™ Muscle Stimulator for Lower Back device is substantially equivalent in design principles to the predicate device, PowerDot PD-01 Muscle Stimulator (K150078), the primary predicate device. The data included in this submission demonstrates design substantial equivalence to the predicate device, the PowerDot PD-01 Muscle Stimulator.

The PowerDot PD-01 Muscle Stimulator (K150078) serves as the primary predicate device for the subject Motive™ Muscle Stimulator for Lower Back. Both the subject and predicate device are battery-powered neuromuscular stimulators intended to stimulate healthy muscles to improve or facilitate muscle performance. The predicate PowerDot PD-01 device is designed to be used together with PowerDot mobile application; the subject Motive™ Muscle Stimulator for Lower Back with the MyMotive mobile application. Both subject and predicate devices use Bluetooth™ Low Energy wireless radio frequency protocol for communication with supported range of mobile devices (such as smartphones and/or tablets) via their respective mobile applications. The predicate PowerDot PD-01 accessories include a US charging cable, two types of hydrogel-based self-adhesive electrode pads and carrying case. The subject Motive™ Muscle Stimulator for Lower Back accessories include a charging cable, a hydrogel-based lower back therapy pad, and conductive gel. The predicate PowerDot PD-01 is intended for the stimulation of healthy muscles to improve or facilitate muscle performance.

In addition to the PowerDot PD-01 predicate device, a reference device is included; the Motive™ Knee Wrap System (K220738). The design, materials, and functional characteristics of the Motive™ Knee Wrap and the Motive™ Muscle Stimulator for Lower Back are substantially the same. Like the previously cleared Motive™ Knee Wrap device, the Motive™ Muscle Stimulator for Lower Back device is a home-based neuromuscular electrical stimulation (NMES) therapeutic system. Both systems are wireless, mobile app-controlled, portable, battery-operated and with one identical NMES treatment mode. Both devices utilize identical patented NMES technology designed to provide strong yet comfortable muscle activation via a power regulated output NMES system that minimizes energy delivery to the targeted treatment area. Both devices employ the same Controller (NMES stimulation generator), a mobile App for delivery of the NMES therapy, RF communications, and similar therapy pads (K230533) to deliver an identical NMES waveform, protocol, and pulse amplitude for the purpose of muscle strengthening.

The Motive™ Knee Wrap System therapy pad (K230533) and Motive™ Muscle Stimulator for Lower Back therapy pad are constructed of identical raw materials, only the geometry of the two therapy pads is different. Both therapy pads are intended for use as a disposable, conductive, and adhesive interface between the user's skin and an electrical muscle stimulator or Controller. The outermost layer of each therapy pad contains a triangle magnetic connector housing for electrical connection to the Controller. Both therapy pads utilize the same silver ink printed onto a PET film to provide electrical conductivity from the Controller to three hydrogel pads which contact the user's skin in proximity to the muscles to be stimulated. Both therapy pad designs have met all applicable biocompatibility, EMC, and electrical safety requirements.

The Motive™ Muscle Stimulator for Lower Back device is substantially equivalent in design and labeling to the primary predicate device and reference device. Nonclinical testing including self-selection study and human factors study performed on the Motive™ Muscle Stimulator for

Lower Back device are sufficient to demonstrate that the subject device is as safe and effective as the legally marketed predicate devices. The technological and labeling differences do not raise new or different questions about safety or effectiveness. The Motive™ Muscle Stimulator for Lower Back device is substantially equivalent to the predicate device.

Table 4 demonstrates the similarities and differences between the subject Motive™ Muscle Stimulator for Lower Back device and the predicate device, PowerDot PD-01, and the reference device, Motive™ Knee Wrap System.

Table 4: Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot® PD-01 Muscle Stimulator (K150078)	Motive™ Knee Wrap (K220738)
Intended Use	The Motive™ Muscle Stimulator for Lower Back NMES System is a battery-powered neuromuscular stimulator, intended to stimulate healthy muscles in order to improve or facilitate muscle performance and, therefore, can be considered as a technique or method for muscle training.	PowerDot PD-01 is a battery-powered neuromuscular stimulator, intended to stimulate healthy muscles in order to improve or facilitate muscle performance and, therefore, can be considered as a technique or method for muscle training.	The Motive™ NMES System is intended for strengthening of the muscles by application of neuromuscular electrical stimulation (NMES) therapy.
Intended Use Environment	Home Use	Home Use	Home Use
Indications for use	The Motive™ Muscle Stimulator for Lower Back NMES System is intended to for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The Motive™ Muscle Stimulator for Lower Back NMES System is not intended to be used in conjunction with therapy or treatment diseases of medical or medical conditions of any kind. The Motive™ NMES System is indicated for adults 22 years of age and older.	The PowerDot PD-01 device, used with PowerDot Mobile Application, is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The PowerDot PD-01 device and PowerDot Mobile Application are not intended to be used in conjunction with therapy or treatment diseases of medical or medical conditions of any kind.	The Motive™ NMES System is intended to strengthen the quadriceps muscle using powered muscle stimulation to provide symptomatic temporary pain relief associated with knee osteoarthritis and improvement of the knee joint mobility when the recommended treatment regimens are followed. In addition, the Motive™ NMES System is indicated for the Retardation or prevention of disuse atrophy. The Motive™ NMES System is indicated for adults 22 years of age and older.
Regulation names and numbers	Powered muscle stimulator, 21 CFR 890.5850 Medical Device Data System, 21 CFR 880.6310	Powered muscle stimulator, 21 CFR 890.5850	Powered muscle stimulator, 21 CFR 890.5850 Medical Device Data System, 21 CFR 880.6310
Product codes and classifications	Powered muscle stimulator, NGX, Class II Medical Device Data System, OUG, Class I	Powered muscle stimulator, NGX, Class II	Powered muscle stimulator, IPF, Class II Medical Device Data System, OUG, Class I

Table 4: Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot® PD-01 Muscle Stimulator (K150078)	Motive™ Knee Wrap (K220738)
Product identifications	Powered muscle stimulator. A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. Medical Device Data System, A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices: (i) The electronic transfer of medical device data; (ii) The electronic storage of medical device data; (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or (iv) The electronic display of medical device data.	Powered muscle stimulator. A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.	Powered muscle stimulator. A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. Medical Device Data System, A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices: (i) The electronic transfer of medical device data; (ii) The electronic storage of medical device data; (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or (iv) The electronic display of medical device data.
Electrical stimulation modalities	"Strength" program therapy	"Strength" program therapy	"Strength" program therapy
System functions	NMES therapy used to stimulate healthy muscles to improve or facilitate muscle performance	NMES therapy used to stimulate healthy muscles to improve or facilitate muscle performance	NMES therapy for knee osteoarthritis pain relief and treatment of disuse atrophy
System components	Controller, Controller charging cable, Mobile Application, Therapy Pad, and Conductive Gel	PowerDot, PowerDot charging cable, Mobile Application, Electrode Lead Wires, and Adhesive Electrode Pads	Controller, Controller charging cable, Mobile Application, Conductive Wrap, Therapy Pad, and Conductive Gel
Controller and PCBA	Controller (pulse generator) consists of a printed-circuit board within a plastic enclosure that mechanically and electrically connects to a Therapy Pad via pogo pins. The Controller is the stimulation generator and the tactile control device for the system. The user can establish a wireless connection between the Controller and their	PowerDot generates and sends electrical signals via electrode pads to your muscles causing them to contract.	Controller (pulse generator) consists of a printed-circuit board within a plastic enclosure that mechanically and electrically connects to a Therapy Pad via pogo pins. The Controller is the stimulation generator and the tactile control device for the system. The user can establish a wireless connection between the Controller and their

Table 4: Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot® PD-01 Muscle Stimulator (K150078)	Motive™ Knee Wrap (K220738)
	mobile device.		mobile device.
Wrap	No Wrap	No Wrap	The Motive™ NMES system utilizes a wrap that is placed on the user's thigh to cover the electrode.
Electrodes / Therapy Pad Description	The Motive™ electrode or Therapy Pad is a disposable, conductive, adhesive, and hydrogel-based interface between the patient's skin and the muscle stimulator (controller or NMES controller). The outermost layer of the Therapy Pad contains a magnetic connector housing for electrical connection to the Controller or muscle stimulator. Refer to K230533.	PowerDot uses round and rectangular-shaped electrode pads to deliver electrical signals to the muscles causing them to contract. The self-adhesive electrode pads are connected to the lead cables via snap-on connectors.	The Motive™ electrode or Therapy Pad is a disposable, conductive, adhesive, and hydrogel-based interface between the patient's skin and the muscle stimulator (controller or NMES controller). The outermost layer of the Therapy Pad contains a magnetic connector housing for electrical connection to the Controller or muscle stimulator. Refer to K230533.
Electrode / Therapy Pad Type	Each therapy pad contains a triangle magnetic connector housing for electrical connection to the Controller via pogo pins. The therapy pad utilizes silver ink printed onto a PET film to provide electrical conductivity from the Controller to the gel pads which contact the user's skin. The therapy pad employs Sekisui hydrogel material (ST-GEL SR).	The PowerDot electrode pads utilize electrode lead wires to connect to the stimulation generator. The electrodes are constructed of carbon pads with a replaceable hydrogel film to connect to the user's skin.	Each therapy pad contains a triangle magnetic connector housing for electrical connection to the Controller via pogo pins. The therapy pad utilizes silver ink printed onto a PET film to provide electrical conductivity from the Controller to the gel pads which contact the user's skin. The therapy pad employs Sekisui hydrogel material (ST-GEL SR).
User Interface	The MyMotive Mobile Application serves as the primary user interface and communication link between the controller and UI. The App includes screens for application of NMES therapy, changing intensities, starting, pausing, and stopping a treatment. The App includes screens for creating a profile, Help, and reminders related to critical tasks such as changing electrodes. Additionally, the App improves therapy compliance through a multi-faceted approach of incentivizing user engagement through a motivational user Dashboard, therapy reminders and a rewards system.	The PowerDot Mobile Application serves as the primary user interface and communication link between the PowerDot and UI. The App includes screens for application of NMES therapy, changing intensities, starting, pausing, and stopping a treatment.	The MyMotive Mobile Application serves as the primary user interface and communication link between the controller and UI. The App includes screens for application of NMES therapy, changing intensities, starting, pausing, and stopping a treatment. The App includes screens for creating a profile, Help, and reminders related to critical tasks such as changing electrodes. Additionally, the App improves therapy compliance through a multi-faceted approach of incentivizing user engagement through a motivational user Dashboard, therapy reminders and a rewards system.

Table 4: Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot® PD-01 Muscle Stimulator (K150078)	Motive™ Knee Wrap (K220738)
TENS therapy	No TENS included	No TENS included	No TENS included
Stimulation pulse characteristics	The patented waveform is a unique, asymmetrical, complex, and monophasic shaped pulse which is designed to provide optimized therapeutic benefits while maximizing comfort and compliance. The unique design features including a longer pulse width (5 ms), monophasic polarity, work cycles, and regulated power output provide a longer duration of muscle contraction within a 20-minute treatment session. The NMES System stimulation pulses have three distinct phases: - Phase 1: Pulse Spike (Rise Time, Peak, and Decay) - Phase 2: Pulse Mesa - Phase 3: Recharge (off period)	The PowerDot stimulation waveform is asymmetrical biphasic with zero mean. The stimulation pulse width is 150-400 µsec for main / positive phase. Maximum treatment time is 60 minutes.	The patented waveform is a unique, asymmetrical, complex, and monophasic shaped pulse which is designed to provide optimized therapeutic benefits while maximizing comfort and compliance. The unique design features including a longer pulse width (5 ms), monophasic polarity, work cycles, and regulated power output provide a longer duration of muscle contraction within a 30-minute treatment session. These unique waveform characteristics lead to the therapeutic benefits of the device reducing the knee pain and improving knee joint functionality. The NMES System stimulation pulses have three distinct phases: - Phase 1: Pulse Spike (Rise Time, Peak, and Decay) - Phase 2: Pulse Mesa - Phase 3: Recharge (off period)
Regulated power output	Using a proprietary technology, the output of stimulation circuit delivers energy to the user at a constant power, independent of the load impedance, hence power regulation during the mesa portion of the pulse.	Regulated voltage output	Using a proprietary technology, the output of stimulation circuit delivers energy to the user at a constant power, independent of the load impedance, hence power regulation during the mesa portion of the pulse.
Patented unique waveform	The stimulation circuit employs a proprietary closed loop feedback technology to regulate energy transferred to the user for stimulation sensation comfort.	Unknown	The stimulation circuit employs a proprietary closed loop feedback technology to regulate energy transferred to the user for stimulation sensation comfort.
Waveform	Asymmetrical, monophasic, complex	Asymmetrical, biphasic with zero mean	Asymmetrical, monophasic, complex

Table 4: Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot® PD-01 Muscle Stimulator (K150078)	Motive™ Knee Wrap (K220738)
Embedded software	The treatment program embedded software is a fundamental component of the system that supports the selection, adjustment, and delivery of the treatment program. The embedded software runs on the Controller and is interfaced with the stimulation pulse generator and App. The Controller software drives the stimulation circuits to generate appropriate waveforms for the protocols and deliver them to the Therapy Pad. The Controller communicates collected data and commands in real-time to the App wirelessly over Bluetooth communications.	The PowerDot treatment program embedded software is a fundamental component of the system that supports the selection, adjustment, and delivery of the treatment program. The embedded software runs on the PowerDot and is interfaced with the stimulation pulse generator and App. The PowerDot software drives the stimulation circuits to generate appropriate waveforms for the protocols and deliver them to the electrodes.	The treatment program embedded software is a fundamental component of the system that supports the selection, adjustment, and delivery of the treatment program. The embedded software runs on the Controller and is interfaced with the stimulation pulse generator and App. The Controller software drives the stimulation circuits to generate appropriate waveforms for the protocols and deliver them to the Therapy Pad. The Controller communicates collected data and commands in real-time to the App wirelessly over Bluetooth communications.
Wireless communications	The Motive™ Muscle Stimulator for Lower Back device incorporates a Bluetooth Low Energy (BLE) connection module to enable wireless communication that can be paired with a Bluetooth enabled mobile device running the App, available from the App stores. The App implements a virtual control panel on the screen of the smart device where on-screen controls are provided to the user.	The PowerDot device incorporates a Bluetooth Low Energy (BLE) connection module to enable wireless communication that can be paired with a Bluetooth enabled mobile device running the App, available from the App stores. The App implements a virtual control panel on the screen of the smart device where on-screen controls are provided to the user.	The Motive™ device incorporates a Bluetooth Low Energy (BLE) connection module to enable wireless communication that can be paired with a Bluetooth enabled mobile device running the App, available from the App stores. The App implements a virtual control panel on the screen of the smart device where on-screen controls are provided to the user.
Medical device data system	A Medical Device Data System (MDDS), Motive™ Web Services are available for the electronic transfer, storage, and display of data sent from and to the controller through the users' App. The portal is hosted on a secure cloud-based server that connects with an internal database using an encrypted API communication.	PowerDot does not employ a Medical Device Data System (MDDS).	A Medical Device Data System (MDDS), Motive™ Web Services are available for the electronic transfer, storage, and display of data sent from and to the controller through the users' App. The portal is hosted on a secure cloud-based server that connects with an internal database using an encrypted API communication.

Table 5 summarizes the technological characteristics of the subject Motive™ Muscle Stimulator for Lower Back device, the predicate PowerDot PD-01 device, and the reference Motive™ Knee Wrap.

Table 5 - Technological characteristics of the subject, predicate, and reference devices

Parameter		**Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)**	**PowerDot® PD-01 Muscle Stimulator (K150078)**	**Motive™ Knee Wrap (K220738)**
510(k) Number		K253478	K150078	K220738
Device Name and Mode		Motive™ Muscle Stimulator for Lower Back	PowerDot® PD-01 Muscle Stimulator	Motive™ Knee Wrap
Manufacturer		Motive Health	Therabody	Same
Power Source(s)†		Single DNK304045: 3.7V; 500mAh; Lithium ion polymer battery	Battery, Li-Po, rechargeable	Same
- Method of Line Current Isolation		No line connection	Unknown	Same
- Patient Leakage Current		---	---	--
- Normal Condition(μA)		4.15	Unknown	Same
- Single Fault Condition (μA)		37.98	Unknown	Same
Number of Output Modes		1	1	Same
Number of Output Channels ††††:	Synchronous or Alternating?	2, Alternating	4, Synchronous	Same
	Method of Channel Isolation	Transistor	Galvanic	Same
Regulated Current or Regulated Voltage?		Regulated Power	Regulated Voltage	Same
Software/Firmware/Microprocessor Control?		Yes	Same	Same
Automatic Overload Trip?		No	Yes	Same
Automatic No-Load Trip?		No	Yes	Same
Automatic Shut Off?		Yes	Same	Same
User Override Control?		Yes	Same	Same
Indicator Display:	On/Off Status?	Yes	Same	Same
	Low Battery?	Yes	Same	Same
	Voltage/Current Level?	No	Yes	Same
Timer Range (minutes)		20 minutes	60 minutes (max)	Same
Compliance with Voluntary Standards?		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10 IEC 62366-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	Same
Compliance with 21 CFR 898?		No	Yes	Same
Weight (lbs., oz.)		1.76 oz / (50g)	0.5 oz / (25g)	Same
Dimensions (in.) [W x H x D]		1.93” x 0.64” x 3.28”	2.4” x 1.7” x 0.5”	Same
Housing Materials and Construction		Molded PC \ ABS Plastic Bayblend FR3010	Plastic injection molding, TPU	Same

Table 6 summarizes the therapy waveform characteristics of the subject Motive™ Muscle Stimulator for Lower Back device, the predicate PowerDot PD-01 device, and the reference Motive™ Knee Wrap.

Table 6 - Waveform parameters of the subject, predicate, and reference devices

Parameter		Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot PD-01 (K150078)	Motive Knee Wrap (K220738)
Mode or Program Name		NMES Strength used to stimulate healthy muscles	Strength	NMES Strength for Pain Therapy
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed Monophasic	Biphasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)		Complex	Rectangular	Same
Maximum Output Voltage (volts) (+/- ____%)		9.4 @ 500 Ω	Not reported by manufacturer	9.3 @ 500 Ω
		16.7 @ 2000 Ω		16.7 @ 2000 Ω
		21.8 @10000 Ω		21.8 @10000 Ω
Maximum Output Current (milliamps) (+/- ____%)		18.7 @ 500 Ω		18.6 @ 500 Ω
		8.3 @ 2000 Ω		8.3 @ 2000 Ω
		2.2 @10000 Ω		2.2 @10000 Ω
Duration of primary (depolarizing) phase† (μsec)		5000		Same
Pulse Duration† (μsec)		5000		Same
Frequency† (Hz) [or Rate† (pps)]		50		Same
For interferential modes only: Beat Frequency† (Hz)		N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
	Phase Duration† (include units),	N/A	N/A	N/A
Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)*		373.9 @500Ω	Not reported by manufacturer	371.9 @500Ω
Maximum Phase Charge, (μC)*		373.9 @500Ω		371.9 @500Ω

Parameter		Proposed Subject Device, Motive™ Muscle Stimulator for Lower Back (K253478)	PowerDot PD-01 (K150078)	Motive Knee Wrap (K220738)
Maximum Current Density,†† (mA/cm², r.m.s.)		0.72 @500Ω (25.8cm^2 square)	Not reported by manufacturer	0.73 @500Ω (25.4cm^2 circle)
Maximum Average Current (average absolute value), mA		18.7 @500Ω		18.6 @500Ω
Maximum Average Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.007 @500Ω (25.8cm^2 square)		0.007 @500Ω (25.4cm^2 circle)
Burst Mode††† (i.e., pulse trains):	(a) Pulses per burst	50		Same
	(b) Bursts per second	0.23		Same
	(c) Burst duration (seconds)	1		Same
	(d) Duty Cycle: Line (b) x Line (c)	0.23		Same
ON Time (seconds)		276		Same
OFF Time (seconds)		924		Same
Additional Features (specify, if applicable)		N/A		N/A

17 Conclusion

The basis for substantial equivalence for the subject Motive™ Muscle Stimulator for Lower Back device and the predicate device is non-clinical data, a self-selection study, human factors test data, and conformity with recognized standards. Stimulation parameters for the PowerDot PD-01 predicate device are not publicly available. The subject Motive™ Muscle Stimulator for Lower Back device's stimulation parameters fall within the range of commonly used NMES devices cleared under 21 CFR 890.5850 and do not raise new or different questions of safety or effectiveness. The subject device's output characteristics were verified through bench and performance testing demonstrating safe and effective operation consistent with legally marketed NMES devices. The hardware and software verification and validation demonstrate that the subject device performs comparably to the predicate device that is marketed for the same intended use. Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the Motive™ Muscle Stimulator for Lower Back device is as safe and effective as, and substantially equivalent to, the predicate device.