May 12, 2022

CyMedica Orthopedics, Inc.
Kereshmeh Shahriari
Vice President, Regulatory, Clinical, & Quality
2120 East 6th Street
Tempe, Arizona 85281

Re: K220738
Trade/Device Name: Motive Knee Wrap
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: March 7, 2022
Received: March 14, 2022

Dear Kereshmeh Shahriari:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

For: CDR Jitendra Virani, MS.
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K220738

Device Name
Motive™ Knee Wrap Device

Indications for Use *(Describe)*
The Motive™ Knee Wrap device is intended to strengthen the quadriceps muscle using powered muscle stimulation to provide symptomatic temporary pain relief associated with knee arthritis.

The Motive™ Knee Wrap device is indicated for adults of 22 years of age and older.

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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510(k) Summary
Motive™ Knee Wrap
CyMedica Orthopedics, Inc.

1 Regulatory Information

1.1 Trade/Proprietary Name:

Motive™ Knee Wrap

1.2 Common Name:

Powered muscle stimulator

1.3 Regulation Names & Numbers:

Powered muscle stimulator, 21 CFR 890.5850

Product Codes:
Code- IPF; Powered muscle stimulator

1.4 Classification:

Powered muscle stimulator: II

1.5 Manufacturer Name:

CyMedica Orthopedics, Inc.
2120 East 6th Street, Suite 8
Tempe, AZ 85281
Telephone (480) 664-1282
FAX (866) 296-2772

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

2 Submission Information

Submission Number: K220738

Date: March 31, 2022

Contact:

Kereshmeh Shahriari
2120 East 6th Street, Suite 8
Tempe, AZ 85281
kereshmeh@cymedicaortho.com
Telephone (480) 664-1282
FAX (866) 296-2772

3 Indications for Use

The Motive Knee Wrap device is intended to strengthen the quadriceps muscle using powered muscle stimulation to provide symptomatic temporary pain relief associated with knee arthritis. The Motive Knee Wrap device is indicated for adults of 22 years of age and older.

4 Device Description

The Motive Knee Wrap device (Motive device) is an over-the-counter (OTC) electrical muscle stimulator (or Neuromuscular Electrical Stimulation (NMES) therapy) for relief of knee pain associated with knee arthritis. The Motive device is used to apply an electrical current through a power regulated output closed-loop feedback NMES system to provide relief of knee pain associated with arthritis. The stimulator continuously contracts quadricep muscle groups for strengthening of the muscles and knee pain relief. The stimulator is placed over the thigh muscle and just above the knee.

4.1 Electrical Muscle Stimulator (NMES therapy)

The device is used to apply a patented unique waveform by means of an electrical current through a power regulated output and closed-loop feedback system to provide relief of knee pain associated with arthritis. The stimulator continuously contracts quadricep muscle groups for strengthening of the muscles and for knee pain relief. Electrical stimulation waveform is generated using a pulse generator or Controller. Electrical stimulation is delivered non-invasively to the treatment site (quadricep muscles of the knee joint) using connected electrodes placed directly on the skin.

4.2 Mobile Application (App)

The electrical stimulation therapy is initiated and managed wirelessly by the User using a mobile application (App) developed for use on smart phones or tablets that interact with the system's pulse generator or Controller.

4.3 Wrap with Smart Panel

The electrical muscle stimulator along with the cutaneous electrodes and wires are incorporated in a Wrap with a Smart Panel™ placed on the thigh and above the knee. Wrap with Smart Panel is worn on the thigh covering quadriceps muscles to apply the NMES therapy. The Wrap is comprised of a modular design including a textile-based wrap and a Smart Panel. The modular Smart Panel is attached to the Wrap by means of a hook and loop interface or other mechanisms. The Smart Panel is an assembly of a Controller (NMES pulse generator), cradle, plastics for hosting the electronics, and four skin contacting snap type electrodes. The Wrap with Smart Panel design is a single size for all size Users and intended for a bilateral use (right and left thigh use independently).

4.4 Wireless Communications

The Motive device incorporates a Bluetooth Low Energy, BLE 4.2 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 buttons are provided to the User.

The Controller is connected to the Smart Panel via a multi-pin interface. The Controller contains the primary safety controls for operation of the device and a push button is available for switching the unit on or off. The power button remains active and can be used in the event

of loss of Bluetooth connection to power on/off the device or start/stop stimulation while performing stimulation sessions. The Controller contains light emitting diodes (LED) which indicate status relating to battery charge, stimulation, and Bluetooth™ activity. Power is derived from a 3.7V Li- Po rechargeable battery pack and the unit can be recharged by using the supplied USB cable.

4.5 Software

The Motive device utilizes an embedded Controller firmware, App software, and Web Services 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 App runs on a mobile platform operating system and communicates with the Controller over a BLE 4.2 connection. The free Motive App is downloaded by the Users from their respective App Stores. The Motive device allows the User to control the NMES therapy program in an easy and intuitive way. It allows the User to select, administer, and adjust the NMES therapy intensities, and manage their health and wellness conditions related to their therapy.

4.6 Controller and the App

The Controller's main function is the NMES therapy stimulation generator and communicating therapy metrics to the App. The Controller contains the primary safety controls for operation of the device. A push button is available for powering the unit on/off or pausing/resuming stimulation. The push button "Stop" control remains active at all times during stimulation and can be used in the event of loss of Bluetooth connection.

Once the App is installed and a wireless connection is established between the Controller and the mobile device (User's phone or tablet), the User can interact with all of the device features. The App downloaded on the User's mobile device provides the graphical user interface and governs the interactions between the controller and the User. The screens and user interface are designed to be intuitive and interactive. Improved User's engagement and compliance through the App are significant design features of the device.

Help and informational screens are provided throughout the App and on specific screens where a User needs to be aware of a feature or condition. Upon downloading the App, the User is guided through chronological screens on the App to perform the following tasks:

- Reading and accepting the Motive App Terms of Use and Conditions
- Creating a User profile
- Pairing the App with the Controller
- Starting the treatment
- Managing the treatment
- Reviewing User's related data and information on the App

4.7 Web Services (API, Database)

A Medical Device Data System (MDDS), the CyMedica Web Services allows for the electronic transfer, storage, retrieval, and display of data sent or received by the Users' App

and Controller. Web Services includes an encrypted database hosted on secure cloud-based servers and an Application Programming Interface (API) allowing the App to send and receive data to read or write to the database and execute logic tasks. Web Services provides persistent storage and retrieval of 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 device Therapy Program 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 device NMES Therapy Program Output Specifications

Waveform	Monophasic
Shape	Asymmetrical, Complex
Pulse width	5 ms
Frequency	50 pps
Maximum current density @ 500Ω	0.7 mA/cm^2 (rms)
Maximum power density (using smallest electrode conductive surface area) @ 500Ω	0.006 W/cm^2
Maximum phase charge @ 500Ω	359.8 µC
Maximum output voltage (V_{RMS}) (±10%) @ 500Ω	9.0 V
Maximum output current (I_{RMS}) (±10%) @ 500Ω	18 mA
Power source	Li-Polymer Battery 950mAh 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, Table 3:

Table 3- Motive NMES Waveform Pulse parameters		
Pulse shape	Asymmetrical, monophasic, and 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 device NMES therapy is recommended to be used twice a day for a minimum of 5 days per week. Each session of NMES therapy is 20 minutes. The therapy is recommended to be applied as long as the knee pain relief is sustained.

8 Summary of Non-Clinical/ Bench Studies

To demonstrate the safety, the Motive device was tested for electrical safety, electromagnetic compatibility, usability, biocompatibility, and risk management requirements.

To demonstrate the safety, the Motive device was tested per the following standards:

- IEC 60601-1: 2005, 3rd Edition, Medical electrical equipment- General requirements for basic safety and essential performance + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- IEC 60601-1-2: 2014-02, 4th Edition, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility requirements
- IEC 60601-2-10: 2012, 2nd Edition, Medical electrical equipment- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulator
- IEC 60601-1-11: 2015, 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 60601-1-6: 2010+ A1:2013, 3rd Edition, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance- Collateral standard: Usability including IEC 62366: Application of usability engineering to medical devices
- IEC 62366: 2007+ A1: 2014, 1st Edition, Medical devices -- Application ofusability engineering to medical devices
- IEC 62304: 2006, 1ST Edition, Medical device software – Software life cycleprocesses
- ISO 10993-1: 2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: 2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization

In addition, the performance of BLE module for wireless co-existence was tested in an environment with equipment operating in the ISM band i.e., Bluetooth and Wi-Fi devices, cellphones, cordless phones, etc. The device met all specified requirements.

BLE module testing was conducted in accordance with the following standards:

- FCC CFR47 Part 15, Subpart C**,** July 2019, Intentional Radiator, §15.247, Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz
- FCC 47CFR PT 15 SPT B, August 2018 Title 47 CFR Part 15 Subpart B: Unintentional Radiators, FCC Part 15, Subpart B [FCC §15.107 & FCC §15.109]

Battery testing was conducted in accordance with IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable applications.

9 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Motive 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 device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and IEC 62304: 2006, 1ST Edition, Medical device software – Software life cycle processes. The software validation tests demonstrated that the software version meets its design requirements.

11 Cybersecurity Controls

Cybersecurity related activities included system assessment and mitigations for potential

cybersecurity hazards and risks on the Motive device performance and data security. Information related to system design features, processes, testing, and controls to manage and mitigate the risks are included in this submission.

Cybersecurity information and supporting documents created and submitted according to the requirements of FDA guidance documents, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014* and *Postmarket Management of Cybersecurity in Medical Devices, December 28, 2016*.

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 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 substantiates the acceptability of the risks identified during the risk assessment activities.
Human Factors information and supporting documents created and submitted according to the requirements of FDA guidance documents, *FDA guidance document, Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*.
Additionally, the Motive device complies with the IEC 60601-1-6: 2010 for usability and IEC 62366: Application of usability engineering to medical devices.

13 Biocompatibility/ Material

The patient contacting materials used in the Motive device components include the Wrap with Smart Panel, electrodes, and electrode gel. The biocompatibility of the Wrap, electrodes, and electrode gel were previously evaluated and cleared under 510(K) submission K163067. 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. From the evaluation and submitted information, the components of the Motive 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 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 electrodes are 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 500, 2k, and 10k ohms, to simulate conditions that the device could counter during use.

16 Comparison of Technological Characteristics with the Predicate Device

CyMedica Orthopedics, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Motive device is substantially equivalent in design principles to the predicate device, CyMedica Orthopedics, Inc. IntelliHab System, K210604, the primary predicate device. The data included in this submission demonstrates design substantial equivalence to the predicate device, IntelliHab System. Both devices utilize the same NMES therapy electrical stimulation waveform and electrodes to deliver the therapy to the quadriceps muscles of the knee. Both devices are indicated for the treatment of knee pain and strengthening of the quadriceps muscle.

The primary predicate IntelliHab system is intended for prescription use and the subject Motive device is intended for over-the-counter (OTC) use. However, both devices are intended for home-use. Data from a self-selection study and human factors study were provided to support the Motive device safety for the OTC use. Additionally, a second predicate device is included, RelieforMe TENS/EMS Device Model UPK-GE01 (K192733) as an OTC device.

The intended use, design, materials, and functional characteristics of the Motive device and the primary predicate device are substantially the same. The subject device and primary predicate device are both intended as home-based use devices. Both devices have the same general purpose and function. Both devices are intended for the same general health population. Both devices utilize the same electrical stimulation therapy to strengthen the quadricep muscle to provide symptomatic temporary knee pain relief. Similar to the primary predicate device, Motive device provides the same NMES waveform, protocol, and pulse amplitude for the purpose of muscle strengthening and knee pain relief. Similar to the primary predicate device, Motive device includes a Wrap, Controller (pulse generator), RF communications, electrodes, and an App for delivery of the NMES therapy.

The Motive device is substantially equivalent in design and labeling to the primary predicate device and secondary predicate device. Nonclinical testing including self-selection study and human factors study performed on the Motive 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. Motive device is substantially equivalent to the predicate devices.

The following table demonstrates the similarities and differences between the subject Motive device and the predicate devices, IntelliHab System and RelieforMe TENS/EMS Device.

TABLE 4- Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Knee Wrap (Motive device), K220738 CyMedica Orthopedics, Inc.	Primary Predicate Device, IntelliHab™ System, K210604 CyMedica Orthopedics, Inc.	2nd Predicate Device, RelieforMe TENS/EMS Device Model UPK-GE01, K192733 UMEHEAL Ltd.
Indications for use	The Motive Knee Wrap device is intended to strengthen the quadriceps muscle using powered muscle stimulation to provide symptomatic temporary pain relief associated with knee arthritis. The Motive Knee Wrap device is indicated for adults of 22 years of age and older.	The IntelliHab system is intended to strengthen the quadricep 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 Intellihab System is indicated for the following: • Retardation or prevention of disuse atrophy • Evaluation of joint mobility by measuring and recording range of motion. The IntelliHab System is indicated for adults of 22 years of age and older.	TENS: 1. It is intended for temporary relief of pain associated with sore and aching muscles in the shoulder, neck, back, waist, abdomen, lower extremities (legs), upper extremities (arms) due to strain from exercise or normal household and work activities. 2. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. EMS: 3. To stimulate healthy muscles to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the intended areas on the body. 4. To be used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
Intended Use	Over-the-Counter (OTC) Home-use	Prescription Home-use	OTC Home-use
Regulation names and numbers	**Powered muscle stimulator**, 21 CFR 890.5850	**Powered muscle stimulator**, 21 CFR 890.5850 **Goniometer, AC-powered**, 21 CFR 888.1500	**Powered muscle stimulator**, 21 CFR 890.5850 **TENS,** 21 CFR 882.5890
Product codes and classifications	**Powered muscle stimulator**, IPF, Class II	**Powered muscle stimulator**, IPF, Class II **Goniometer, AC-powered**, KQX, Class I	**Powered muscle stimulator**, IPF, Class II **TENS,** GZJ and NUH, Class II

TABLE 4- Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Knee Wrap (Motive device), K220738 CyMedica Orthopedics, Inc.	Primary Predicate Device, IntelliHab™ System, K210604 CyMedica Orthopedics, Inc.	2nd Predicate Device, RelieforMe TENS/EMS Device Model UPK-GE01, K192733 UMEHEAL Ltd.
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.	**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. **Goniometer, AC-powered**, A goniometer is an AC-powered or battery powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint.	**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. **TENS,** A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.
Electrical stimulation modalities	NMES "Strength" program therapy	NMES "Strength" program therapy	NMES and TENS therapies
System components	Controller, Controller changing cable, App, Wrap with Smart Panel, electrodes, and electrode gel	Controller, Controller changing cable, App, conductive wrap, electrodes, and electrode gel	Controller and electrodes
Controller and PCBA	Controller (pulse generator) consists of a printed-circuit board within a plastic enclosure that docks in a wrap docking receptacle via a 16-pin interface. 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 mobile device.	Same	Unknown
Wrap	The Wrap design includes a modular design of a basic textile-based wrap and a removable Smart Panel where all the electronics, wires, and electrodes are included in the Smart Panel. • Wrap with Smart Panel is single size. • A single Wrap with Smart Panel can provide treatment for both right and left knees (not simultaneously).	The Wrap is one piece only and includes integrated electronics, wires, and accelerometers Wrap is not washable. • Wrap comes in different sizes. • Two designated right and left wraps are required to provide the treatment for the right knee or left knee (not simultaneously).	No wrap

TABLE 4- Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Knee Wrap (Motive device), K220738 CyMedica Orthopedics, Inc.	Primary Predicate Device, IntelliHab™ System, K210604 CyMedica Orthopedics, Inc.	2nd Predicate Device, RelieforMe TENS/EMS Device Model UPK-GE01, K192733 UMEHEAL Ltd.
Electrodes	Three snap type connected electrodes integrated with the Smart Panel of the Wrap. One 2" diameter electrode is required to activate the Vastous Medialis Oblique (VMO) muscle and two 2" x 3.5" electrodes for Rectus Femoris (RF) muscle. Although only three electrodes are required to provide the therapy, in the Motive device setup steps, Users are instructed to install 4 electrodes (2 VMO electrodes) so they can apply the right and left knee therapies when desired.	Three wire connected or pigtail electrodes integrated with the conductive wrap. One 2x2" electrode for VMO muscle and two 2" x 3.5" electrodes for RF muscle.	Unknown
User Interface	The User's App 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, initial device setup guide, 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.	Same UI design	Unknown
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. These unique waveform characteristics lead to the therapeutic benefits of the device reducing the knee pain and	Same	Unknown

TABLE 4- Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Knee Wrap (Motive device), K220738 CyMedica Orthopedics, Inc.	Primary Predicate Device, IntelliHab™ System, K210604 CyMedica Orthopedics, Inc.	2nd Predicate Device, RelieforMe TENS/EMS Device Model UPK-GE01, K192733 UMEHEAL Ltd.
	improving knee joint functionality. The Moive NMES 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.	Same	Unknown
Closed loop feedback system	The stimulation circuit employs a proprietary closed loop feedback technology to regulate energy transferred to the User for stimulation sensation comfort.	Same	None
Waveform	Asymmetrical, monophasic, complex	Same	Unknown
Pulse width (µsec)	5000 µsec	Same	250-400 µs, NMES 4-300 µs, TENS
Pulse Train	50 Hz	Same	1 –100 Hz, NMES 1-1200, TENS
Maximum Output Voltage (volts, rms) (+/- %) @ 2k Ω	16.7 V	Same	65 V
Maximum Output Current (mA, rms) (+/- %) @ 2k Ω	8.3 mA	Same	32.5 mA
Net Charge (microcoulombs (µC) per pulse)	359.8 µC @500Ω	Same	Unknown

TABLE 4- Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Knee Wrap (Motive device), K220738 CyMedica Orthopedics, Inc.	Primary Predicate Device, IntelliHab™ System, K210604 CyMedica Orthopedics, Inc.	2nd Predicate Device, RelieforMe TENS/EMS Device Model UPK-GE01, K192733 UMEHEAL Ltd.
Maximum Phase Charge, (µC)	359.8 µC @500Ω	Same	48.8 µC @500Ω, NMES 36.6 µC @500Ω, TENS
Maximum Current Density (mA/cm²,r.m.s.)	0.9 mA @500Ω	Same	Unknown
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)	0.009 W/cm² @500Ω	Same	Unknown
Integrated digital goniometer	No goniometer	In addition to an electrical muscle stimulator, IntelliHab System includes an integrated digital goniometer for measurement of knee joint range of motion (ROM) to evaluate joint mobility. The device includes two accelerometers located in a conductive wrap and IntelliHab Controller allowing for the measurement of knee joint extension and flexion degrees or range of motion measurement. The measured flexion, extension, and ROM angles are displayed and stored in the IntelliHab patient's App.	No goniometer
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 prescribed protocols and deliver them to the	Same	Unknown

TABLE 4- Substantial Equivalence Comparison	Proposed Subject Device, Motive™ Knee Wrap (Motive device), K220738 CyMedica Orthopedics, Inc.	Primary Predicate Device, IntelliHab™ System, K210604 CyMedica Orthopedics, Inc.	2nd Predicate Device, RelieforMe TENS/EMS Device Model UPK-GE01, K192733 UMEHEAL Ltd.
	electrode interface. The power button, with integrated LED indicator, on the Controller is used for powering the Controller On/Off and Pause/Resume an active treatment; the button is always active and can be used in the event of loss of Bluetooth connection to the mobile device to pause or abort therapy. The Controller communicates collected data and commands in real-time to the App wirelessly over Bluetooth communications.		
Wireless communications	Motive device incorporates a Bluetooth Low Energy, BLE 4.2 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 buttons are provided to the user. The Controller is connected to the Smart Panel via a multi-pin interface. The Controller contains the primary safety controls for operation of the device and a push button is available for switching the unit on or off. The power button remains active and can be used in the event of loss of Bluetooth connection to power on/off the device or start/stop stimulation while performing stimulation sessions. The Controller contains light emitting diodes (LED) which indicate status relating to battery charge, stimulation, and Bluetooth™ activity. Power is derived from a 3.7V Li-Po rechargeable battery pack.	Same	None

The following table summarizes the subject Motive device and the predicated devices, IntelliHab System and RelieforMe technological characteristics:

Table 5- Technological characteristics of the subject device and predicate devices

Parameter		Motive Knee Wrap	IntelliHab System	RelieforMe
510(k) Number		K220738	K210604	K192733
Device Name and Mode		Motive NMES	Intellihab NMES	RelieforMe TENS/EMS
Manufacturer		CyMedica Orthopedics	Same	UMEHEAL Ltd.
Power Source(s)†		Single VD434053: 3.7V; 1000mAh; Lithium ion polymer battery	Same	Battery powered
- Method of Line Current Isolation		No line connection	Same	Unknown
- Patient Leakage Current		---	---	--
- Normal Condition(µA)		4.88	Same	Unknown
- Single Fault Condition (µA)		8.00	Same	Unknown
Number of Output Modes		One (NMES)	Same	2
Number of Output Channels ††††:	Synchronous or Alternating?	1, Alternating	Same	1
	Method of Channel Isolation	1, Transistor	Same	1
Regulated Current or Regulated Voltage?		Regulated Power	Same	Voltage
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes
Automatic Overload Trip?		No	No	No
Automatic No-Load Trip?		No	No	No
Automatic Shut Off?		Yes	Yes	Yes
User Override Control?		Yes, Stop Buttons	Yes	Yes, Off button stops treatment immediately
Indicator Display:	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	Yes
	Voltage/Current Level?	No	No	No
Timer Range (minutes)		20-open	Same	Unknown
Compliance with Voluntary Standards?		Yes. IEC 60601-2-10:2012 Part 2-10; IEC 60601-1-11:2015 Part 1-11; IEC 60601-1-6:2010; ISO 10993-1:2009 Part 1	Yes, Same standards	Unknown
Compliance with 21 CFR 898?		Yes	Yes	Unknown

Weight (lbs., oz.)	1.76 oz. (50g)	Same	Unknown
Dimensions (in.) [W x H x D]	1.93” x 0.64” x 3.28”	Same	Unknown
Housing Materials and Construction	Molded PC\ABS Plastic Bayblend FR3010	Same	Unknown

The following table summarizes the subject Motive device and the predicated device, IntelliHab System therapy waveform characteristics:

Table 6- Motive NMES Waveform & IntelliHab NMES Waveform Parameters				
NMES Waveform Parameters		**Subject device, Motive NMES program**	**Predicate device, IntelliHab NMES program, K210604**	**Discussion of similarities and differences**
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed Monophasic	Pulsed Monophasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)		Complex	Complex	Same
Maximum Output Voltage (volts, rms) (+/-_____%)		9.3 @500Ω	9.0 @500Ω	Similar
		16.7 @ 2 k Ω	16.2 @ 2 k Ω	Similar
		21.8 @10 k Ω	21.1 @10 k Ω	Similar
Maximum Output Current (mA, rms) (+/- _%)		18.6 @500Ω	18.0 @500Ω	Similar
		8.3 @ 2 k Ω	8.1 @ 2 k Ω	Similar
		2.2 @10 k Ω	2.1 @10 k Ω	Similar
Duration of primary (depolarizing) phase (µsec)		5000	5000	Same
Pulse Duration (µsec)		5000	5000	Same
Frequency (Hz) [or Rate (pps)]		50	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	N/A	N/A	N/A
Net Charge (microcoulombs (µC) per pulse) (If zero, state method of achieving zero net charge.)		359.8 @500Ω	359.8 @500Ω	Same

Maximum Phase Charge, (μC)		359.8 @500Ω	359.8 @500Ω	Same
Maximum Current Density (mA/cm², r.m.s.)		0.9 @500Ω	0.7 @500Ω	Similar
Maximum Average Current (average absolute value), mA		18.6 @500Ω	18.0 @500Ω	Similar
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)		0.009 @500Ω	0.006 @500Ω	Similar
Burst Mode	(a) Pulses per burst	50	50	Same
	(b) Bursts per second	0.23	0.23	Same
	(c) Burst duration (seconds)	1	1	Same
	(d) Duty Cycle: Line (b) x Line (c)	0.23	0.23	Same
ON Time (seconds)		276	276	Same
OFF Time (seconds)		924	924	Same
Additional Features (specify, if applicable)		N/A	N/A	N/A

17 Summary of Clinical Study

Subject Motive device utilizes the same NMES waveform and protocol as the predicate device CyMedica IntelliHab System, K210604. Clinical data submitted in the predicate device application, IntelliHab System, K210604 applies to the subject Motive device.

18 Conclusion

The basis for substantial equivalence for the Motive device and the predicate devices is non-clinical data, a self-selection study, human factors test data, and conformity with recognized standards. The hardware and software verification and validation demonstrate that the subject device performs comparably to the predicate devices that are 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 device is as safe and effective as, and substantially equivalent to, the predicate devices.