March 22, 2023

CyMedica Orthopedics, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K230533
Trade/Device Name: Motive™ Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 27, 2023
Received: February 27, 2023

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 (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,

Tushar Bansal -S

for Heather Dean, Ph.D
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

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)*
K230533

Device Name
Motive(TM) Electrode

Indications for Use *(Describe)*
The Motive™ Electrode is intended for use as a disposable, conductive, and adhesive interface between the user's skin and an electrical muscle stimulator.
Motive Electrode is intended 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™ Electrode
CyMedica Orthopedics, Inc.

1 Regulatory Information

1.1 Trade/Proprietary Name: Motive™ Electrode

1.2 Common Name: Electrode, Cutaneous

1.3 Regulation Names & Numbers: Cutaneous Electrode, 21 CFR 882.1320

Product Codes:
Code- GXY; Electrode, Cutaneous

1.4 Classification: Class II

1.5 Manufacturer Name: **CyMedica Orthopedics, Inc.**

2120 East 6t Street, Suite 8
Tempe, AZ 85288
Telephone (480) 664-1282
FAX (866) 296-2772

1.6 Predicate Device Information:

Trade name – ASCEND Electrode, NeuroMetrix, Inc.
Common name – Electrode, Cutaneous
Code – GXY; Electrode, Cutaneous
Classification name – Cutaneous Electrode, 21 CFR 882.1320
510(k) Number – K140586

These devices are reviewed by the Neuromodulation and Physical Medicine Devices (DHT5B).

2 Submission Information

Submission Number:

Date: February 15, 2023

Contact: Kereshmeh Shahriari
2120 East 6th Street, Suite 8
Tempe, AZ 85288
kereshmeh@cymedicaortho.com

Telephone (480) 664-1282
FAX (866) 296-2772

3 Intended Use/Indications for Use

The Motive™ Electrode is intended for use as a disposable, conductive, and adhesive interface between the user's skin and an electrical muscle stimulator.
Motive Electrode is intended for adults of 22 years of age and older.

4 Device Description

The Motive Electrode provides an electrically conductive interface between a neuromuscular electrical stimulator (muscle stimulator) and a user's skin. The Motive Electrode is provided non-sterile, is designed and intended for single patient use only, multiple application use, and is disposable. The electrode sheet is to be worn on the thigh covering the quadriceps muscles to apply electrical stimulation therapy when connected to a muscle stimulator. The electrodes are conductive pads that contact the skin. The electrical stimulation impulses are delivered through the electrodes on the skin in direct proximity to the muscles to be stimulated.
The Motive Electrode consists of multiple layers. The skin-contacting layer of the electrode sheet is comprised of three separate medical grade, self-adhering, biocompatible, and conductive hydrogel (gel) pads. These gel pads are placed on a single polyester or polyethylene terephthalate (PET) sheet. These gel pads include two rectangular 2 inch x 4 inch (5.1 x 10.2 cm) and one circular, 2.165 inch diameter (5.5 cm) pads.
The outermost layer of the electrode contains a magnetic connector housing for electrical connection to the muscle stimulator. Silver ink printed conductive electrical traces on the PET film are utilized to provide electrical conductivity from the muscle stimulator to the gel pads.
When not in use, the electrode sheet is covered by a paper-backed release liner.

5 Summary of Non-Clinical/ Bench Studies

Verification of the Motive Electrode include electrical and mechanical tests to show that it meets its target specifications over a range of operating and storage conditions. Verification and performance testing further demonstrate that it meets user needs as reflected in the functional specification.

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

- 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

6 Biocompatibility Testing

The patient contacting materials in the Motive™ Electrode include a conductive hydrogel used in the form of gel pads. The hydrogel is placed on a Polyethylene Terephthalate (PET) backing liner. PET is a known biocompatible material. The hydrogel is medical grade, self-adhering, and biocompatible. The gel pads (hydrogel) are skin contacting. A biocompatibility test was conducted on the patient contacting materials per the following standards. The test results were acceptable, and the materials were considered biocompatible.

- 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 irritation and sensitization

7 Shelf-Life

The Motive Electrode has a 6-month shelf life. Accelerated aging shelf-life testing was performed to ensure that the Motive Electrode performs as intended over the course of its labeled shelf-life.

8 Summary of Non-Clinical/ Bench Studies

Verification of the Motive Electrode included electrical and mechanical tests. The electrical tests demonstrated the electrodes impedance measurements were acceptable and electrodes performed effectively and safely in delivering transmitting electrical stimulation to the user's tissue. The electrical tests also demonstrated that the Motive Electrode's Maximum Current Density and Maximum Average Power Density were acceptable and similar to the predicate device, ASCEND Electrode.

Mechanical testing demonstrated that the electrodes maintained the mechanical integrity for different layers and components of the electrode sheet.

Visual evaluation demonstrated that the Motive Electrodes were intact and interfaced with the muscle stimulator.

Verification and performance testing further demonstrate that the Motive Electrodes meet user's needs as reflected in the product specification.

9 Comparison of Technological Characteristics with the Predicate Device

The predicate device for Motive Electrode is ASCEND Electrode manufactured by NeuroMetrix, Inc., 510(k) NUMBER K140586. The Motive Electrode and ASCEND Electrode have the same intended use. Both are intended as disposable, single-patient for multiple application use electrodes with an adhesive conductive hydrogel interface to deliver treatment from an electrical stimulator to the User's skin. Both are multi-layer electrode sheet designs housing multiple individual electrodes in a pre-defined geometry. Both are substantially equivalent in composition and material, consisting of flex silver pads or traces printed onto a plastic film base sheet.

The primary difference between the two devices is that the Motive Electrode consists of three electrodes compared to the ASCEND Electrode's four electrodes. The shape and surface area of the Motive Electrodes are within range of the predicate ASCEND Electrodes. The individual predicate ASCEND Electrodes contain a smaller surface area (36 by 46 mm, surface area of 1656 mm^2). In contrast, the smallest Motive Electrode contains a larger surface area (50.8 mm diameter circle, surface area of 2026 mm^2).

Table 1 compares design details of the Motive Electrode to the predicate ASCEND Electrode:

Table 1: Motive Electrode and predicate ASCEND Electrode comparison

	Subject Device	Predicate Device	
	Motive Electrode CyMedica Orthopedics, Inc. 510(k), K230533	**ASCEND Electrode, NeuroMetrix, Inc. 510(k), K140586**	**Comparison**
General Characteristics			
Intended Use	The Motive™ Electrode is intended for use as a disposable, conductive, and adhesive interface between the user's skin and an electrical muscle stimulator.	The ASCEND Electrode is intended for use as disposable, conductive, adhesive interface between the user's skin and a transcutaneous electrical nerve stimulator.	N/A
Number of Electrodes	3, two rectangular and one circular	Not publicly available	Any differences do not raise any issue in equivalency of both as it relates to safety or efficacy.
Sterile	Non-sterile	Non-sterile	N/A
Single-Patient Use	Yes	Yes	N/A
Number of applications	Multiple	Not publicly available	N/A
Shelf life	6 months	Not publicly available	N/A
Technical Characteristics			
Substrate	Polyethylene terephthalate (PET) film	Not publicly available	N/A
Conductor	Conductive silver ink traces	Not publicly available	N/A
Conductive interface	Medical grade conductive hydrogel	Not publicly available	N/A
Connector	Pogo pin connector array	Not publicly available	Any differences do not raise any issue in equivalency of both as it relates to safety or efficacy.
Overall Dimensions	15.6 x 21.8 cm, total area 211 cm^2, includes three electrodes	Not publicly available	Any differences do not raise any issue in equivalency of both as it relates to safety or efficacy.
Conductive Surface Dimensions	Two rectangular pads 5.1 x 10.2 cm and one circular pad 5.1 cm diameter, total area 124.5 cm^2	Not publicly available	Any differences do not raise any issue in equivalency of both as it relates to safety or efficacy.

10 Conclusion

The summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that the Motive Electrode is as safe, as effective, and performs as well as the predicate device.