April 25, 2022

Myolyn, LLC
Matthew Bellman
Chief Technology Officer
6931 NW 22nd Street, Suite A
Gainesville, Florida 32653-1231

Re: K213925
Trade/Device Name: MyoCycle MC-2 (Home / Home + / Pro / Pro +)
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: January 7, 2022
Received: January 10, 2022

Dear Matthew Bellman:

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,

Amber T. Ballard -S

Amber Ballard, PhD
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)*
K213925

Device Name
MyoCycle MC-2 (Home / Pro / Home + / Pro +)

Indications for Use *(Describe)*
The MyoCycle is intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion
5. Muscle re-education

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(1) Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Company: MYOLYN, INC
6931 NW 22ND Street, Suite A
Gainesville, FL 32653
Phone: (352) 354-2749

Contact person: Matthew Bellman, PhD
Chief Technology Officer
Phone: (352) 204-9066 x101
E-mail: mjbellman@myolyn.com

Date prepared: April 25, 2022

(2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name:

Proprietary name:	MyoCycle MC-2 (Home / Home + / Pro / Pro +)
Common name:	Functional electrical stimulation
Classification name:	External functional neuromuscular stimulator
Device class:	2
Classification product code:	GZI
Classification panel:	Neurology
Regulation number:	882.5810

(3) Identification of the legally marketed device to which the submitter claims equivalence:

Manufacturer:	MYOLYN
Product:	MyoCycle MC-HP-1 (Home / Pro)
510(k) number:	K170132
Device class:	2

(4) A description of the device that is subject of the premarket notification submission:

The MyoCycle is a stationary Functional electrical stimulation (FES) cycle ergometer which is composed of:

1. a motorized cycle ergometer
2. an FES controller / stimulator
3. a stimulation cable which connects the controller / stimulator to cutaneous electrodes (at maximum 20 cutaneous electrodes for 10 channels)
4. cutaneous electrodes

This system allows a person with impaired lower extremity movement to undertake cycle ergometry both actively (utilized FES evoked lower extremity muscle contractions) and passively

(utilizing power developed by the ergometer's motor). The electric motor inside the MyoCycle ensures that the pedals always rotate at 35 revolutions per minute (r/min) (isokinetic cycling), so it automatically assists or resists the patient, depending on the magnitude and direction of the torque applied to the crank by the patient.

The system software has four different configurations:

1. Pro – allows for multiple users by storing unique user data that can be accessed by a unique user identification code; extended FES parameter adjustability; up to six channels of stimulation
2. Home – only stores data for one user; limited FES parameter adjustability; up to six channels of stimulation
3. Pro Plus (+) – same as Pro but allows for up to ten channels of stimulation and uses patient cabling with additional leads
4. Home Plus (+) – same as Home but allows for up to ten channels of stimulation and uses patient cabling with additional leads

(5) Indications for Use Statement:

The MyoCycle MC-2 device's Indications for Use (IFU) Statement is substantially equivalent to that of the predicate device, the MyoCycle MC-HP-1 (K170132), as described in the table below.

MyoCycle MC-2 IFU Statement	**MyoCycle MC-HP-1 (K170132) IFU Statement**
The MyoCycle is intended for general rehabilitation for: 1. Relaxation of muscle spasms 2. Prevention or retardation of disuse atrophy 3. Increasing local blood circulation 4. Maintaining or increasing range of motion **5. Muscle re-education**	The MyoCycle is intended for general rehabilitation for: 1. Relaxation of muscle spasms 2. Prevention or retardation of disuse atrophy 3. Increasing local blood circulation 4. Maintaining or increasing range of motion

NOTE: THE SAME INDICATIONS FOR USE AS THE EXISTING MYOCYCLE ARE PROPOSED HOWEVER THE MUSCLE RE-EDUCATION INDICATION FROM FDA'S POWERED MUSCLE STIMULATOR GUIDANCE DOCUMENT HAS BEEN ADDED.

The MyoCycle is for prescription use only.

(6) Technological Characteristics

The function of the MyoCycle MC-2 is substantially equivalent to the predicate device; however, there are certain technological similarities and differences, as described below:

Technology	**MyoCycle MC-2**	**MyoCycle MC-HP-1 (K170132)**
Power source (energy used)	Mains power	Mains power
Controller	Uses embedded microcontrollers running custom software with an Android OS interface	Uses embedded microcontrollers running custom software
Stimulator (energy delivered)	0-140 mA charge balanced stimulator	0-126 mA charge balanced stimulator
Stimulation pulse width	20 to 500 microseconds	Not publicly available
Stimulation frequency	5 to 100 Hz	Not publicly available
Stimulation channels	Up to 10 channels	Up to 6 channels
Muscles available for stimulation	Bilateral quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, abdominals, erector spinae	Not publicly available
Flywheel	Uses motor to create flywheel effect with reduced weight and space	Uses motor to create flywheel effect with reduced weight and space
Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	Utilizes motor to provide assistance during passive cycling	Utilizes motor to provide assistance during passive cycling
Touchscreen interface	Utilizes a 10-inch touchscreen graphical user interface (GUI)	Not publicly available
Wireless communications	Utilizes an integrated 802.11 a/b/g/n/ac WLAN (Wi-Fi), Bluetooth, and Bluetooth Low Energy (BLE) module	Not publicly available
Database interface	Utilizes database interface for storage and retrieval of	

	patient therapy settings and storage of session logs.	Not publicly available

(b) Performance data

Testing to determine equivalence has been primarily composed of the following tests:

Test or procedure	**Description**
Review of user documentation for predicate device	Ensure that equivalent functionality is specified and implemented in the new device.
Review of 510(k) submission for predicate device	Confirm technical specifications for completion of predicate details in comparison tables.
Output characteristic measurement of new device	Confirm technical specifications for completion of new device details in comparison tables.
Conduct of system testing	Conduct system testing to verify performance to specification.

The system testing described above made general use of the following recognized consensus standards to ensure specific risks were reduced to acceptable levels:

Recognition Number	**Standards Organization**	**Standard Designation Number and Date**	**Title of Standard**
19-4	ANSI AAMI	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-36	IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

			disturbances - Requirements and tests
5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
19-38	IEC	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	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
17-16	IEC	60601-2-10 Edition 2.1 2016-04	Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

Discussion

The intended use of the MyoCycle MC-2 is substantially equivalent to that of the predicate device MyoCycle MC-HP-1 (K170132). The MyoCycle MC-2 has an indication for use, namely, "muscle re-education," which the predicate device does not claim. However, this indication is a standard indication for use for Powered Muscle Stimulators according to the guidance document entitled, "Guidance Document for Powered Muscle Stimulator 510(k)s," dated June 9, 1999. Furthermore, the addition of this indication with respect to the predicate does not raise any new questions of safety and effectiveness.

The MyoCycle MC-2 has similar technological characteristics and output specifications to those of the predicate device MyoCycle MC-HP-1 (K170132). Specifically, the MC-2 device has up to four additional stimulation channels with a wider range of stimulation parameters and a larger touchscreen interface. The different characteristics and specifications do not raise new questions of safety and effectiveness. MYOLYN's non-clinical testing, including bench testing against recognized consensus standards, have demonstrated that the MC-2 device is as safe and effective as the predicate device and is therefore substantially equivalent.

MYOLYN concludes that:

The intended use of the MyoCycle is substantially equivalent to that of the predicate device.

The MyoCycle has similar output characteristics to those of the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

MYOLYN's performance testing has demonstrated that the MyoCycle is as safe and effective for the intended use as the predicate device and is therefore substantially equivalent.