DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 25, 2017

Myolyn, LLC
Matthew Bellman
Chief Technology Officer
7731 W. Newberry Rd., Suite A-2
Gainesville, Florida 32606

Re: K170132
Trade/Device Name: Myocycle Home, Myocycle Pro
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: March 21, 2017
Received: March 23, 2017

Dear Mr. 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170132

Device Name
MyoCycle Home, MyoCycle 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

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, LLC
7731 W. Newberry. Rd., Suite A-2
Gainesville, FL 32606
Phone: (352) 354-2749

Contact person: Matthew Bellman, PhD
Chief Technology Officer
Phone: (850) 832-1842
E-mail: mjbellman@myolyn.com

Date prepared: 04-12-2017

(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 Home, MyoCycle Pro
Common name:	Functional electrical stimulation (FES) cycle ergometer
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:	Restorative Therapies Inc.
Product:	RT300-S
510(k) number:	K050036
Device class:	2

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

The MyoCycle is a stationary 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 12 cutaneous electrodes for 6 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 operates in two modes:

1. Pro mode – allows for multiple users by storing unique user data that can be accessed by a unique user identification code
2. Home mode – only stores data for one user

(5) Indications for Use Statement:

The MyoCycle's Indications for Use (IFU) Statement is substantially equivalent to that of the predicate device, the RT300-S (K050036), as described in the table below. The MyoCycle does not have the same IFU Statement as the RT300-SP (pediatric version).

MyoCycle IFU Statement	**RT300-S (K050036) 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	The RT300-S (adult version) and RT300-SP (pediatric version) are 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 The RT300-SP (pediatric version), is intended for population ages 4 to 12 years.

The MyoCycle is for prescription use only.

(6) Technological Characteristics

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

Technology	**MyoCycle**	**RT300-S (K050036)**
Power source (energy used)	Mains power	Mains power
Controller	Uses embedded microcontrollers running custom software	Based on Pocket PC running custom software
Stimulator (energy delivered)	0-126 mA charge balanced stimulator	0-140 mA charge balanced stimulator

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

(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.
Testing with lay operators	The MyoCycle was validated with five lay operators using the device with an able bodied, simulated patient.
Testing with clinician operators	The MyoCycle was validated with seven clinician operators using the device with six spinal cord injured patients.
Testing with patient operators	The MyoCycle was validated with five spinal cord injured patients using the device without assistance.

As part of the system testing described above, the MyoCycle met the following recognized consensus standards:

Recognition Number	Standards Organization	Standard Designation Number and Date	Title of Standard
17-11	IEC	60601-2-10 Edition 2.0 2012-06	Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators
19-4	AAMI ANSI	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)
19-8	IEC	60601-1-2 Edition 4.0 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
19-14	IEC	60601-1-11 Edition 2.0 2015-01	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
19-16	AAMI ANSI	HA60601-1-11:2015	Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment (IEC 60601-1-11:2015 MOD)

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.