DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 11, 2017

Restorative Therapies, Inc.
Andrew Barriskill
CEO
1434 Fleet St.
Baltimore, Maryland 21231

Re: K162470
Trade/Device Name: RT300 FES Cycle Ergometer
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: June 7, 2017
Received: June 8, 2017

Dear Mr. Barriskill:

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)*
K162470

Device Name
RT300 FES Cycle Ergometer

Indications for Use *(Describe)*
The RT300 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 RT300 pediatric version is intended for population ages 4 to 12 years.
The RT300 is intended for use with a surface electrical stimulation garment for population ages 12 and above.
The RT300 is for prescription use only.

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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RT300 510(k) Summary

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

Restorative Therapies Inc
1434 Fleet St
Baltimore, MD 21231

Contact Person: Andrew Barriskill
Phone: 800 609-9166

Prepared on July 16, 2016.

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

Proprietary name: RT300 FES Cycle Ergometer
Common name: External Functional Neuromuscular Stimulator
Classification name: External Functional Neuromuscular Stimulator (21 CFR 882.5810)
Regulatory Class: II
Product Code: GZI

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

RESTORATIVE THERAPIES, INC. product: "RT300", K090750
RESTORATIVE THERAPIES, INC. product: "Xcite Clinical Station", K160614

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

The RT300 is a Functional Electrical Stimulation (FES) cycle ergometer which is composed of:

1. A motorized leg cycle ergometer (RTI part number SA100047 for adults and SA100044 for children)

2. An optional motorized arm crank (RTI part number PP102663)

3. An FES controller with up to two 6 channel stimulators (RTI part number SA216172)

4. Up to 5 additional wireless single channel stimulators (RTI part number SA216128)

5. A leg and optional arm stimulation cable which connects the stimulator to cutaneous electrodes

6. Cutaneous electrodes (up to 24 electrodes for up to 12 stimulation channels)

7. An interface to a remote database for the storage and retrieval of therapy settings and the storage of therapy session logs

8. An interface to a pulse oximeter for the display and recording of pulse and SpO2 levels and provision of alarming based on the data

9. A garment incorporating electrodes for lower extremity cycling in population ages 12 and above (RTI part number FA105486)

This system allows a person with impaired upper or lower extremity movement to undertake cycle ergometry both actively (utilizing FES evoked upper or lower extremity muscle contractions) and passively (utilizing power developed by the ergometer's motor). The system combines a Windows based tablet, cycle ergometer, and stimulators in a single unit. The system is controlled by the Sage software that runs on the tablet. The Sage software delivers stimulation to the designated muscle groups in a coordinated fashion based on angle information from the ergometer. In doing so the system facilitates a smooth cycling motion throughout the therapy session.

(5) Indications for Use:

The RT300 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 RT300 pediatric version is intended for population ages 4 to 12 years.
The RT300 is intended for use with a surface electrical stimulation garment for population ages 12 and above.

The RT300 is for prescription use only.

The Indications for Use described in the numbered items above are not identical to the predicate device, however, the differences do not alter the intended

therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for general rehabilitation.

(6) Technological Characteristics
The function of the RT300 is the same as the predicate devices however there are certain technological similarities and differences as described below:

Technology	RT300	RT300 predicate: K090750	Xcite predicate K160614
Ergometer	Cycle ergometer	Cycle ergometer	No ergometer
Power source (energy used)	Mains power and rechargeable battery for RT50 stimulators	Mains power and rechargeable battery for RT50 stimulators	Mains power and rechargeable battery for RT60 and RT50 stimulators
Controller	Based on Tablet PC running custom software.	Based on Pocket PC running custom software.	Based on tablet PC running custom software.
Stimulator (energy delivered)	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator. Optionally, the RT300 can accommodate two 6-channel stimulators for a total of 12 channels.	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator.	Up to 2 DC powered 0-140mA 6 channel charge balanced stimulators ("RT60"s).
Stimulation pulse width	Up to 3,000usec	Up to 500usec	Up to 500usec
Additional stimulation channels	Up to 5 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.	Up to 5 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.	Up to 4 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.
Stand alone stimulation mode	Wireless battery powered stimulation channels may be used in standalone mode without the cycle ergometer.	Wireless battery powered stimulation channels may be used in standalone mode without the cycle ergometer.	Always used in standalone stimulation mode.
Stimwear	Stimwear garment	Stimwear garment	No stimwear

Technology	RT300	RT300 predicate: K090750	Xcite predicate K160614
garment	incorporating electrodes available for lower extremity cycling, ages 12 and above.	incorporating electrodes available for lower extremity cycling, ages 12 and above.	garment.
Muscles available for stimulation	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp, abdominals, erector spinae.	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp, abdominals, erector spinae.	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist extensors and flexors, grasp, abdominals, erector spinae.
Flywheel	Uses leg / arm crank motor to create flywheel effect with reduced weight and space.	Uses leg / arm crank motor to create flywheel effect with reduced weight and space.	N/A
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.	N/A
Passive cycling	Utilizes motor to provide assistance during passive cycling.	Utilizes motor to provide assistance during passive cycling.	N/A
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.
Motorized arm crank	Allows active / passive arm cycling with FES	Allows active / passive arm cycling with FES	N/A
Pulse oximeter interface	Utilize pulse and SpO2 data for display, recording and alarming	Utilize pulse and SpO2 data for display, recording and alarming	Utilize pulse and SpO2 data for display, recording and alarming
Bilateral or Unilateral stimulation	Uses bilateral or unilateral stimulation.	Uses bilateral or unilateral stimulation.	Uses bilateral or unilateral stimulation.

Technology	RT300	RT300 predicate: K090750	Xcite predicate K160614
Indications	1.Relaxation of muscle spasms 2.Prevention or retardation of disuse atrophy 3.Increasing local blood circulation; and 4.Maintaining or increasing range of motion 5. Muscle re-education The RT300 pediatric version is intended for population ages 4 to 12 years. The RT300 is intended for use with a surface electrical stimulation garment for population ages 12 and above. The RT300 is for prescription use only.	1.Relaxation of muscle spasms 2.Prevention or retardation of disuse atrophy 3.Increasing local blood circulation; and 4.Maintaining or increasing range of motion The RT300 pediatric version is intended for population ages 4 to 12 years. The RT300 is intended for use with a surface electrical stimulation garment for population ages 12 and above. The RT300 is for prescription use only.	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

Table 1 Device technology comparison

(b) Performance data

Non clinical testing to determine equivalence has been primarily composed of the following tests:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the RT300, consisting of the tablet, leg ergometer, arm ergometer, 2 RT60s and stimulation cable. The system complies with IEC 60601-1, IEC 60601-2-10, and IEC 60601-1-11 standards for safety and IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: The software for this device was considered "moderate" level

of concern, since a failure of latent flaw in the software could directly result in minor injury to the patient or operator.

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.

Clinical Testing

Clinical testing consisted of a multi-arm study with patients serving as their own control. The protocol's objective was to evaluate the safety and effectiveness of external functional neuromuscular stimulators operating at high pulse widths (500-3000 usec) stimulation. Subjects used multi-muscle, high frequency, and pulse width with the RT300 stimulator to generate neuromuscular activity. Subjects were evaluated for 4 interventions; Cycling with Lower Extremity NMES (NeuroMuscular Electrical Stimulation), Lower Extremity NMES, Trunk NMES, and Upper Extremity NMES. Additionally pediatric subjects were assessed

<u>Cycling with Lower Extremity NMES</u>

Intervention:

Fifteen patients (15) undertook activity based therapy using NMES during cycling on an RT300 cycle.

Primary safety endpoint:

The primary safety endpoint consisted of treatment-related adverse reactions, normal erythema, blancheable erythema, muscle strain, joint strain, or fracture.

Effectiveness

The primary endpoint for the Cycling intervention focused on the risk assessment of cycling with high pulse width (500-3000 usec, with 8 patients receiving the maximum of 3000us) stimulation. Fifteen (15) patients completed 434 cycling sessions - 3 had normal erythema and none had an adverse reaction, blancheable erythema, muscle strain, joint strain nor fracture. Therefore this intervention met its primary endpoint with no adverse reactions or other injuries.

<u>Lower Extremity NMES</u>

Intervention:

Thirty-three (33) patients undertook activity based therapy using NMES during the following motor tasks: lying supine, sit to stand, standing.

Primary effectiveness endpoint:
Clinically significant improvements in functional outcome measures. These measures included evaluation using the Adult Neuromuscular Recovery Scale (NRS), Berg Balance Scale, Biodex Dynamometer Torque test for Force Production from Maximum Voluntary Contractions (MVC), Overground Standing Test.

Primary safety endpoint:
The primary safety endpoint consisted of treatment-related adverse reactions, normal erythema, blancheable erythema, muscle strain, joint strain, or fracture.

Effectiveness
The primary endpoint for the Lower Extremity intervention focused on the changes to the outcome measures after intervention with high pulse width (500-3000 usec, with 10 patients receiving the maximum of 3000us). Twenty-three (23) patients increased their NRS by 16% (average pre assessment score of 5.43 to average post of 6.45), their lower extremity NRS by 11% (3.27 to 3.71); 15 patients increased their Berg scores by 47% (average pre assessment score of 6.8 to average post of 10); MVC torque increased for 8 lower extremity muscle groups (Right and Left knee extensors, Right and Left plantarflexors and Right and Left dorsiflexors) in an average of 9 patients by a minimum of 152% (average torque in Nm at pre assessment of 3.5 to a post assessment of 7.13) increase in right plantarflexor torque output to a maximum 3796% (average torque in Nm at pre assessment of 0.1 to a post of 21.87) for left plantarflexor output, and 8 patients increased their Overground Standing Test times by 7108% (average pre time standing of 0 to average post time of 300 seconds). Therefore this intervention met its primary endpoint of an increase in all outcome measures.

Safety
After 920 sessions twenty-seven (27) patients experienced no adverse reactions, 8 patients experienced normal erythema, 1 patient experienced blancheable erythema and none experienced muscle strain, joint strain nor fracture.

<u>Trunk NMES</u>
Intervention:
Thirteen (13) patients undertook activity based therapy using NMES during the following motor tasks: sit, sit up and reverse sit up.

Primary effectiveness endpoint:
Clinically significant improvements in functional outcome measures. These measures included evaluation using the Adult Neuromuscular Recovery Scale

(NRS), Berg Balance Scale, Modified Functional Reach, Independent Sitting, and Trunk Scale.

Primary safety endpoint:
The primary safety endpoint consisted of treatment-related adverse reactions, normal erythema, blancheable erythema, muscle strain, joint strain, or fracture.

Effectiveness
The primary endpoint for the Lower Extremity intervention focused on the changes to the outcome measures after intervention with high pulse width (500-3000 usec with 2 patients receiving the maximum of 3000us) stimulation. Eleven (11) patients increased their NRS by 18% (average pre assessment score of 5.26 to average post of 5.81), 5 patients increased their Berg scores by 50% (average pre assessment score of 9 to average post of 14); Modified reach scale increased 9 patients by 196% (average reach in inches at pre assessment of 6.45 to a post assessment of 18); Independent Sitting times increased in 3 patients 26583% (pre assessment time of 0 seconds to a post of 600 seconds); Trunk scale increased in 2 patients by 180% (pre assessment score of 0 to a post of 4). Therefore this intervention met its primary endpoint of an increase in all outcome measures.

Safety
After 172 sessions ten (10) patients experienced no adverse reactions, 3 patients experienced normal erythema, 1 patient experienced blancheable erythema and none experienced muscle strain, joint strain nor fracture.

<u>Upper Extremity NMES</u>
Intervention:
Fourteen (14) patients undertook activity based therapy using NMES during different motor tasks including reaching, grasping, pressing overhead, manipulating materials, and opening a door.

Primary effectiveness endpoint:
Clinically significant improvements in functional outcome measures. These measures included evaluation using the Adult Neuromuscular Recovery Scale (NRS), Modified Functional Reach, Bilateral Upper Extremity Basic Strength, and Modified Ashworth Upper Extremity scale.

Primary safety endpoint:
The primary safety endpoint consisted of treatment-related adverse reactions, normal erythema, blancheable erythema, muscle strain, joint strain, or fracture.

Effectiveness
The primary endpoint for the Upper Extremity intervention focused on the outcome measures after intervention with high pulse width (500-3000 usec with 1

patient receiving the maximum of 3000us) stimulation. Eleven (11) patients increased their NRS by 8% (average pre assessment score of 3.91 to average post of 4.08), Modified reach scale increased in 4 patients by 122% (average reach in inches at pre assessment of 1.5 to a post assessment of 5.8); Bilateral Upper Extremity Basic Strength increased in 3 patients by 8% (pre assessment scale 2 to 2.1 post assessment) and Modified Ashworth Upper Extremity scale increased in 3 patients by 3%. Therefore this intervention met its primary endpoint of an increase in all outcome measures.

Safety
After 65 sessions seven (7) patients experienced no adverse reactions, 8 patients experienced normal erythema, and none experienced blancheable erythema, muscle strain, joint strain nor fracture.

Pediatric NMES
Intervention:
8 (eight) patients between the ages of 2 and 13 yrs old undertook activity based therapy for the upper, trunk and lower extremities using NMES during the different motor tasks (eg. reaching, grasping, standing).

Primary effectiveness endpoint:
Clinically significant improvements in functional outcome measures. These measures included evaluation using the Pediatric Neuromuscular Recovery Scale (NRS) and Segmental Assessment of Trunk Control (SATCo).

Primary safety endpoint:
The primary safety endpoint consisted of treatment-related adverse reactions, normal erythema, blancheable erythema, muscle strain, joint strain, or fracture.

Effectiveness
The primary endpoint for the Lower Extremity intervention focused on the outcome measures after intervention with high pulse width (500-1000 usec with all 8 patients receiving the maximum of 1000us) stimulation. Four (4) patients increased their NRS by 88% (average pre assessment score of 2.38 to average post of 4.13) and 3 patients increased their SATCo by 35% (pre assessment score of 8 to a post of 10.7)

Safety
After 324 sessions 8 patients experienced no adverse reactions, 6 patients experienced normal erythema, and none experienced blancheable erythema, muscle strain, joint strain nor fracture.

Summary

Based on the clinical performance as documented in the clinical testing, the RT300 was found to have a safety and effectiveness profile that is similar to the predicate device

RTI concludes that:

The RT300 has the same intended use as the RT300 predicate device.

The RT300 with available wider stimulation pulses utilizes the same stimulators and control system as the predicate device including controller, stimulators, motor controller and drive assembly. The different technological characteristics do not raise new questions of safety and effectiveness.

In conclusion, RTI's clinical testing has demonstrated that the RT300 is as safe and effective as the predicate devices.