K090750

AUG 0 5 2009

510(k) Summary

Note: Changes from K072398 RT300 Summary of Safety and Effectiveness are shown in italics.

RT300 Summary of Safety and Effectiveness

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

Andrew Barriskill
Restorative Therapies Inc
907 South Lakewood Ave
Baltimore, MD 21224

Phone: 800 609-9166

Prepared on June 22nd 2009.

(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: Powered Muscle Stimulator
Classification name: External functional neuromuscular stimulator

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

RESTORATIVE THERAPIES, INC. product: "RT300", K072398, a class 2 device

THERAPEUTIC ALLIANCES, INC. product: "ERGYS", K841112, a class 2 device. **Relates to Stimwear only.**

HASOMED GMBH product: "REHASTIM & REHAMOVE", K073237, a class 2 device. **Relates to stand alone stimulator use only.**

(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 built in 6 channel*** stimulator (RTI part number SA100090)
4 up to 5 additional wireless single channel stimulators (RTI part number FA106897)
5 a leg and optional arm stimulation cable (either bilateral or unilateral) which connects the controller / stimulator to cutaneous electrodes
6 cutaneous electrodes (***up to 22 electrodes for up to 11 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 stimwear 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).

(5) Statement of the intended use of the device:
The RT300 and pediatric versions 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 is for prescription use only.
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.

(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**	**Predicate K072398**	**Predicate K841112**	**Predicate K073237**
Power source (energy used)	Mains power and rechargeable battery for RT50 stimulators	Mains power	N/A	N/A
Controller	Based on Pocket PC	Based on Pocket PC	N/A	N/A

Technology	RT300	Predicate K072398	Predicate K841112	Predicate K073237
	running custom software.	running custom software.		
Stimulator (energy delivered)	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator.	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator.	N/A	N/A
Additional stimulation channels	***Up to 5 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.***	Additional stimulation channels not available.	N/A	N/A
Stand alone stimulation mode	***Wireless battery powered stimulation channels may be used in stand alone mode with out the cycle ergometer.***	Stand alone mode not available.	N/A	Stimulator "can be used as a portable or stationary device for training and rehabilitation applications."
Stimwear garment	***Stimwear garment incorporating electrodes available for low extremity cycling, ages 12 and above.***	Stimwear garment not available.	Available stimwear garment incorporating electrodes.	N/A
Muscles available for stimulation	Quadriceps, hamstrings, gluteals, gastroc, anterior	Quadriceps, hamstrings, gluteals, gastroc,	N/A	N/A

Technology	RT300	Predicate K072398	Predicate K841112	Predicate K073237
	tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp, ***abdominals, erector spinae.***	anterior tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp		
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	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	N/A
Passive cycling	Utilizes motor to provide assistance during passive cycling.	Utilizes motor to provide assistance during passive cycling.	N/A	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.	N/A	N/A

Technology	RT300	Predicate K072398	Predicate K841112	Predicate K073237
Motorized arm crank	Allows active / passive arm cycling with FES	Allows active / passive arm cycling with FES	N/A	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	N/A	N/A
Bilateral or Unilateral stimulation	Uses bilateral or unilateral stimulation cables.	Uses bilateral or unilateral stimulation cables.	N/A	N/A

Table 1 Device technology comparison

(b) Performance data

Non clinical 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.

Clinical Test	Description
Testing the RT50 stimulation	The RT300 with 5 additional RT50 stimulation channels was validated with five able bodied individuals. The RT50 in standalone mode was validated with five able bodied individuals.

Clinical Test	Description
Testing additional muscle groups.	The RT50 clinical testing included testing of abdominal and erector spinae stimulation .
Testing the Stimwear garment	The RT300 with the Stimwear garment was validated on one able bodied individual.

RTI concludes that:

The RT300 has the same intended use as the predicate device. The RT300 has the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of providing up to 5 additional channels of electrical stimulation utilizing the RT50 to the upper and lower extremities, erector spinae and abdominal muscle groups has been demonstrated during validation testing. The safety and effectiveness of utilizing Stimwear and carbon electrodes has been demonstrated during validation testing.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Restorative Therapies, Inc
% Andrew Barriskill
CEO
907 South Lakewood Ave
Baltimore, MD 21224

AUG 0 5 2009

Re: K090750
Trade Name: RT300 Functional Electrical Stimulation (FES) Cycle Ergometer
Regulation Number: 21 CFR §882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: July 15, 2009
Received: July 16, 2009

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K090750

Device Name: RT300 Functional Electrical Stimulation (FES) cycle ergometer

Indications For Use:

The RT300 (adult and pediatric version) are intended for general rehabilitation for:

a. Relaxation of muscle spasms
b. Prevention or retardation of disuse atrophy
c. Increasing local blood circulation
d. Maintaining or increasing range of motion

The RT300 is for prescription use only.
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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090750