K072398

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

NOV 2 1 2007

Prepared on July 20th, 2007.

(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: Powered Muscle Stimulator

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

RESTORATIVE THERAPIES, INC. product: "RT300", K071486, a class 2 device

(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 / stimulator (RTI part number SA100090)
4 a leg and optional arm stimulation cable (either bilateral or unilateral) which connects the controller / stimulator to cutaneous electrodes
5 cutaneous electrodes (up to 12 electrodes for up to 6 stimulation channels)
6 an interface to a remote database for the storage and retrieval of therapy settings and the storage of therapy session logs
7 an interface to a pulse oximeter for the display and recording of pulse and SpO2 levels and provision of alarming based on the data

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 adult 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 pediatric version is intended for population ages 4 to 12 years.

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

Technology	**RT300**	**Predicate K071486**
Power source (energy used)	Mains power	Mains power
Controller	Based on Pocket PC running custom software.	Based on Pocket PC running custom software.
Stimulator (energy delivered)	0-140mA charge balanced stimulator	0-140mA charge balanced stimulator
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.
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.
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.
Motorized arm crank	Allows active / passive arm cycling with FES	Allows active / passive arm cycling without FES
Pulse oximeter interface	Utilize pulse and SpO2 data for display, recording and alarming	Utilize pulse and SpO2 data for display, recording and alarming
Bilateral or Unilateral	Uses bilateral or	Uses bilateral or

stimulation	unilateral stimulation cables.	unilateral stimulation cables.

(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 upper extremity stimulation	The RT300 upper extremity stimulation was validated with five able bodied individuals.

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 both bilateral and unilateral electrical stimulation to the upper extremities 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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Restorative Therapies, Inc.
% Mr. Andrew Barriskill
CEO
907 South Lakewood Avenue
Baltimore, Maryland 21224

NOV 2 1 2007

Re: K072398
Trade/Device Name: RT300
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: August 21, 2007
Received: August 27, 2007

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072398

Device Name: RT300

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072398