K073237

5. 510(k) Summary

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

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DEC 2 7 2007

Prepared on august 1th 2007

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

Proprietary name:	RehaStim	of HASOMED GmbH
	RehaMove (movement exerciser with arm crank, includes RehaStim)	of HASOMED GmbH
Common Name:	Powered Muscle Stimulator	
Classification Name:	Powered Muscle Stimulator	

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

Manufacture:	Restorative Therapies Inc.
Product:	"RT300-S" ; "RT300-SP",
K-number:	K060032
Class:	class 2 device
Product Code:	GZI

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

The RehaMove is a portable Functional Electrical Stimulation (FES) system based on a cycle ergometer and a stimulator. It consists of:

(1) a motorized movement exerciser (MOTOTMed viva II) produced by Reck-company

(2) for alternative training of upper extremities a motorized arm crank with same characteristics can be used

(3) FES – stimulation controller RehaStim, that generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. The RehaStim can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications.

(4) an information cable (RS232) connects the RehaStim and the movement exerciser

(5) 4 electrode cables (at maximum 16 cutaneous electrodes for 8 channels) connected the RehaStim with the electrodes on the skin

(6) an USB interface to connect the RehaStim to PC

(7) The stand-alone mode of RehaStim allows training without movement exerciser.

The system RehaMove allows training for person with impaired functions of lower and upper extremities in two modes:

(1) active mode, using FES support for muscle contractions and if necessary motor power of movement exerciser

(2) passive mode – only movement by motorized movement exerciser

(5) Statement of the intended use of the device:

Both the RehaStim and RehaMove 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

(6) Technological Characteristics

The functions of the RehaMove and RehaStim are the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RehaStim/RehaMove	RT300-S
Power Source	Mains / Battery Power	Mains Power
Controller	Uses custom controller running custom software	Based on Pocket PC running custom software
Stimulator (energy delivered)	0-126mA charge balanced stimulator with rectangular impulses	0-140mA charge balanced stimulator with rectangular impulses
patient part	Type: BF	Type: BF
movement exerciser	RehaMove: Uses motor to create flywheel effect with reduced weight and space	Uses motor to create flywheel effect with reduced weight and space
Arm crank	Arm crank in the same possible like upper extremities	Arm crank in the same possible like upper extremities
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	RehaMove: 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

Table 6-1 Technological similarities and differences

(7) Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent functionality was implemented in RehaMove.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables
Output characteristic measurement of new device	The RehaMove / RehaStim device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 7-1 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the to the premarket notification.

HASOMED concludes that:

Both the RehaMove and RehaStim have the same intended use and 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 using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim and RehaMove and many clinical applications.

The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED´s clinical and non- clinical testing have demonstrated that the RehaStim and RehaMove are 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

DEC 27 2007

Hasomed GmbH
% Underwriters Laboratories, Inc.
Mr. Casey Conry
Senior Project Engineer
1285 Walt Whitman Road
Melville, NY 11747

Re: K073237
Trade/Device Name: Rehastim & Rehamove
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: December 17, 2007
Received: December 20, 2007

Dear Mr. Conry:

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

4. Indications for Use

510(k) Number (if known): -

Device Name: RehaMove
RehaStim (stand alone)

Indications for Use:

Both the RehaMove and RehaStim 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

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

Barbara Bruen MD

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

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