DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 3, 2017

HASOMED Gmbh
Matthias Ueltzen
Quality Management & Regulatory Affairs
Paul-Ecke-Str. 1
Magdeburg, SA 39114
Germany

Re: K162683
Trade/Device Name: RehaStim 2
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: December 22, 2016
Received: December 27, 2016

Dear Mr. Ueltzen:

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)*
K162683

Device Name
RehaStim 2

Indications for Use *(Describe)*
The RehaStim 2 stimulator is intended for general rehabilitation

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 RehaStim 2 is an External Functional Neuromuscular Stimulator, designed for use as stand-alone device as well as in combination with exercise equipment for walking and cycling applications, that has been validated for compatibility by HASOMED GmbH and should be used under the supervision of a clinician.

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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510(k) Summary

I. SUBMITTER

510k Submitter: Hasomed GmbH

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Prepared 2016-09-22, revised 2016-11-22, 2017-01-20, 2017-01-26, and 2017-02-02.

II. DEVICE

Modification to an existing device

Proprietary name: RehaStim 2

Common Name: Powered Muscle Stimulator

Classification Name: Powered Muscle Stimulator

Device Class: class 2 device

Classification: Neurology

Product code: GZI

III. PREDICATE DEVICE

Device 1 – primary predicate

Proprietary name: RehaStim 2;

	RehaMove 2 (RehaStim 2 with movement exerciser)
510(k):	K112844
Device Class:	class 2 device
Classification:	Neurology
Product code:	GZI
Common Name:	Powered Muscle Stimulator

Device 2

Proprietary name:	RehaStim 2;
	ErigoPro (FES)
510(k):	K132416
Device Class:	class 2 device
Classification:	Neurology
Product code:	GZI, BXB, INQ
Common Name:	Powered Muscle Stimulator

IV. DEVICE DESCRIPTION

RehaStim 2 is a 8 channel External Functional Neuromuscular Stimulator. RehaStim 2 can be used as a stand-alone device or in combination with an external motion trainer for cycling or walking applications, that has been validated for compatibility by HASOMED GmbH and should be used under the supervision of a clinician.

A connection cable enables the RehaStim 2 to receive motion data from the external movement exerciser device for walking or cycling applications in order to apply electrical stimulation synchronized with the movement. The stimulation is performed according to the motion data. The stimulation parameters can be configured inside the stimulator.

Electrode lead wires are used to connect RehaStim2 output and electrodes on skin.

V. INDICATIONS FOR USE

The RehaStim 2 stimulator 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 RehaStim 2 is an External Functional Neuromuscular Stimulator, designed for use as stand-alone device as well as in combination with exercise equipment for walking and cycling applications, that has been validated for compatibility by HASOMED GmbH and should be used under the supervision of a clinician.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The functions of the RehaStim 2 (2016) are the same as the predicate devices ErigoPro (FES), RehaMove 2, and RehaStim 2 remained the same, however there are certain technological similarities and differences as described below:

Technology	**RehaStim 2 (2016)**	**RehaStim 2 / ErigoPro (FES)** **K132416**	**RehaStim 2 / RehaMove 2** **K112844 primary predicate**
Power Source	AC and/or storage battery: Power supply: cincon tr30m ac-cording to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC: **ErigoPro:** Total System: 110-230V 800VA Includes RehaStim2 power supply: cincon tr30m according to EN60601-1	AC and/or storage battery: Power supply: cincon tr30m ac-cording to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,

		RehaStim2 (only): AC: power supply: cincon tr30m ac-cording to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	
Power input (charging)	9V, 3A, max. 30 W	RehaStim2: 9V, 3A, max. 30 W	9V, 3A, max. 30 W
Operation time	ca. 90 min	ErigoPro: No limitation by battery RehaStim2: ca. 90 min	ca. 90 min
Charging time	ca. 180 min	ErigoPro: N/A RehaStim2: ca. 180 min	ca. 180 min
Controller	uses custom controller using embedded Linux as basis operating system, running custom software	uses custom controller using embedded Linux as basis operating system, running custom software ErigoPro: RehaStim2 is controlled by	uses custom controller using embedded Linux as basis operating system, running custom software

		ErigoPro Control Panel	
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses / same hardware	0-130mA charge balanced stimulator with rectangular impulses / same hardware	0-130mA charge balanced stimulator with rectangular impulses / same hardware
Pulse width	max. 500 µs	max. 500 µs	max. 500 µs
Stimulation frequency	max. 50 Hz	max. 50 Hz	max. 50 Hz
Number of channels	8	8	8
Electrodes	HASOMED's RehaTrodes only	HASOMED's RehaTrodes only ErigoPro: HASOMED's electrodes with "distributed by Hocoma" label	HASOMED's RehaTrodes only
FES00200 RehaTrode	2.0" x 3.5", rectangle	2.0" x 3.5", rectangle	2.0" x 3.5", rectangle
FES00201 RehaTrode	3.0" x 5.0", rectangle	3.0" x 5.0", rectangle	3.0" x 5.0", rectangle
FES00202 RehaTrode	1.5" x 2.5" oval	1.5" x 2.5" oval	1.5" x 2.5" oval
Applied part	Type BF	Type BF	Type BF
Movement	RehaStim 2 (2016)	ErigoPro: uses	RehaMove: Uses

exerciser	is intended for combination with different movement exercisers for walking and cycling applications	motor to robotic leg movement and cyclic leg loading for early functional mobilization	motor to create flywheel effect with reduced weight and space
Communication interface	FES 2 + FES 3; FES 3-bidirectional communication, controlling of movement exerciser functionality interface allows for combination with different devices	RehaStim2: FES 2 + FES 3; FES 3-bidirectional communication, controlling of movement exerciser functionality ErigoPro: RS2-ErigoMode - bidirectional communication, controlling of FES, synchronized with the ErigoPro device	FES 2 + FES 3; FES 3-bidirectional communication, controlling of movement exerciser functionality
Control philosophy of matching the combined devices	Complete stimulation control implemented in RehaStim 2, movement exerciser delivers motion data for synchronization of stimulation and movement	Parts of stimulation control implemented in Erigo device	Complete stimulation control implemented in RehaStim 2, movement exerciser delivers motion data for synchronization of stimulation and movement

Patient position	As usual in the movement exerciser device combined with	Verticalization table for early rehabilitation	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	Exercise equipment: Utilizes motor to provide assistance during passive walking or cycling	ErigoPro (FES): Utilizes motor for robotic leg movement and cyclic leg loading	RehaMove: 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	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 1 Technological similarities and differences

The difference is in the control philosophy of the device combinations: In RehaStim 2 / RehaMove 2 the complete stimulation know-how is in the controller of the stimulation device RehaStim 2. In ErigoPro (FES) some of the stimulation control is implemented in the Erigo control. In the new device, stimulation control is completely implemented in the stimulation device and an interface is used for input of motion data into the stimulator. The stimulation is performed according to the motion data. The motion data are delivered via a serial interface (USB, FTDI) as percentage of full gait cycle at a rate of about 10 ms from the exerciser to the stimulator. A proprietary protocol is used. Based on this gait information, stimulation is activated at pre-defined values to the muscles needed according to the actual phase of gait. A proprietary testing protocol conducted by Hasomed GmbH is being used for validation and verification of RehaStim 2 for use with an exercise equipment. Hasomed will conduct risk hazard analysis to determine if additional testing (e.g. electrical safety, EMC, verification and validation) is necessary to ensure safety and effectiveness when using the RehaStim 2 with an exercise equipment.

VII. PERFORMANCE DATA

The RehaStim 2 (2016) and both predicate devices (ErigoPro (FES) and RehaStim 2 / RehaMove 2) have the same intended use and the same output characteristics. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of the single stimulator device RehaStim 2 is extensively demonstrated by using the device for many years.

The safety and effectiveness of combining the electrostimulation device RehaStim 2 with movement exercisers or with devices for early functional mobilization of bedridden patients have been extensively demonstrated by the ongoing use of the predicate devices RehaStim 2 / ErigoPro (FES) and RehaStim 2 / RehaMove 2, respectively.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 (2016). For combining the device with exercise equipment for walking and cycling applications, clear assessment instructions for verification and validation ensure, that no new questions of safety and effectiveness can be introduced by the combination of the products.

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent functionality was implemented.
Review of 510(k) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables (see above)
Output characteristic measurement of new device	The RehaStim 2 (2016) device was tested and technically compared with the predicate devices.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 2 Performance data

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

VIII. CONCLUSIONS

Since the intended use of the predicate devices is the same and the therapeutic parameters did not change, no clinical testing was required. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the device will perform as intended in the specified use conditions. Hasomed concludes that the device performs comparably to the predicate devices that are currently marketed for the same intended use.