



Food and Drug Administration
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September 18, 2015

Recovr, Inc
% Kathryn Cole
Principle
Translational Science Solutions LLC
92 Hasell Street, Suite 401
Charleston, South Carolina 29401

Re: K151446
Trade/Device Name: Recovr Rehabilitation System
Regulatory Class: Unclassified
Product Code: LXJ
Dated: August 4, 2015
Received: August 10, 2015

Dear Kathryn Cole:

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 yours,

Carlos L. Pena -SDA

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151446

Device Name

Recovr Rehabilitation System

Indications for Use (Describe)

The Recovr Rehabilitation System is software for use with the Microsoft Kinect motion tracking system that is indicated to support physical rehabilitation of adults in the clinic and at home via performance of therapist-assigned reach exercises for the upper extremities. Patient assessment, exercise guidance, and approval by the medical professional are required prior to use.

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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5.0 510(K) SUMMARY

Submission Date: September 17, 2015

Submitter Information:

Submitted By: Recovr, Inc.
Post Office Box 772
Clemson, SC 29633

Contact Person: Austen Hayes, MS
Chief Executive Officer
Tel: (843) 425-1606
Email: austen@recovrinc.com

Device Information:

Trade Name: Recovr Rehabilitation System

Common Name: Software system utilizing optical position recording for rehabilitation exercises

Classification Name: System, Optical Position/Movement Recording (Product Code LXJ)

Regulatory Class: Unclassified

Predicate Device: Jintronix Rehabilitation System (K130847)
Jintronix, Inc.
Unclassified (Product Code LXJ)

Device Description: The Recovr Rehabilitation System (RRS) is a software system that presents games to facilitate the completion of therapist designed and prescribed upper extremity repetitive reaching exercises and that collects data for the therapist on the user's game play. The system was designed in collaboration with an experienced neurorehabilitation occupational therapist and rehabilitation research team. The RRS is intended for use in the clinic or at home. Patient assessment, exercise guidance, and approval by the medical professional are required prior to use.

The system consists of software, a computer, a primary display monitor, a secondary monitor, and a Microsoft Kinect motion-tracking sensor. Users sit on a bench or stand 6-8 feet away from the primary display monitor. The Kinect sensor is placed along the top or bottom edge of the primary display monitor, and the therapist controls the system from a secondary monitor, mouse, and keyboard off to the side of the primary display monitor. The games are based on a traditional carnival

shooting gallery, with targets that pop-up to present reaching tasks. The virtual reality environment incorporates video game principles to engage and motivate users to perform the amount of rehabilitation assigned by the rehabilitation therapist. The system collects data on participant movement and actions throughout each session that allows therapists to track participant performance and improvement across therapy sessions.

The device is not supplied sterile or intended to be sterilized by the operator prior to use, and is not intended for single use.

Indications for Use:

The Recovr Rehabilitation System is software for use with the Microsoft Kinect motion tracking system that is indicated to support physical rehabilitation of adults in the clinic and at home via performance of therapist-assigned reach exercises for the upper extremities. Patient assessment, exercise guidance, and approval by the medical professional are required prior to use.

The Indications for Use statement for RRS is not identical to the predicate device in that the Indications for Use for the subject device do not include "remotely accessible patient performance metrics for the medical professional" at this time. That minor difference does not affect the intended use of the subject device as a software system utilizing optical position recording for physical rehabilitation exercises nor do they affect the safety and effectiveness of the device relative to the predicate when used as labeled.

Comparison to Predicate Device:

The RRS and the predicate Jintronix Rehabilitation System (JRS) are substantially equivalent in terms of intended use and performance and technology. Both platforms are software systems utilizing optical position recording for physical rehabilitation exercises that use the Microsoft Kinect motion tracking system. Both systems require patient assessment and exercise guidance from a clinical or medical professional prior to any exercise prescription. Both devices track the movements assigned by the clinician, providing audio-visual feedback and graphic representations of the user movement, as well as reporting to the clinician on kinematic parameters like velocity and joint angular changes during movement. The devices are also identical in safety, as they are software platforms for use with the Microsoft Kinect motion tracking system. At this point in time, the subject device does not include remotely accessible patient performance metrics for the

medical professional, but that does not affect the safety or effectiveness of the device compared to the predicate.

Performance Testing:

No mandatory performance standards have been established for this device (Section 514 of the Act). Software testing was conducted to verify performance in accordance with FDA's May 2005 guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, as there is no risk of harm to the user or operator in the case of device failure or latent flaw.

No biocompatibility, electrical safety and electromagnetic compatibility, animal, or clinical testing was deemed necessary to support the current finding of substantial equivalence to the predicate Jintronix device.

Conclusion:

The RRS falls within the generic type of device regulated by the LXJ Product Code (System, Optical Position/Movement Recording). Differences in the design and presentation of the RRS from the predicate device do not affect the safety, effectiveness, or performance of the subject device for its intended use. Software verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. Therefore, the RRS is substantially equivalent to the Jintronix Rehabilitation System.