May 10, 2018

UINCARE Corp.
% Geum Hyeon Kim
Lead Consultant
DT&S Co., Ltd.
#1206, Mario Tower, 28, Digital-ro 30-gil
Guro-gu, Seoul, 08389 Kr

Re: K172882
Trade/Device Name: UINCARE Home
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring Exercise Equipment
Regulatory Class: Class II
Product Code: LXJ
Dated: April 2, 2018
Received: April 26, 2018

Dear Geum Hyeon Kim:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -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)*
K172882

Device Name
UINCARE HOME

Indications for Use *(Describe)*
The UINCARE software system used with the Microsoft Kinect is intended to be used to support the physical rehabilitation of adults in the clinic or at home. The system includes rehabilitation exercises for the lower and upper extremities with audio- visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

A-603, 131, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506, Republic of Korea
Tel) +82-2-6265-0944, Fax) +82-2-6265-0945

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

April.02. 2018

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: UINCARE Corp.
- Address: A-603, 131, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506, Republic of Korea
- Telephone No.: +82-2-6265-0944
- Fax No.: +82-2-6265-0945

3. Submission Correspondent

- Name of company: DT&S Co., Ltd.
- Address: #1206, Mario Tower, 28, Digital-ro 30-gil, Guro-gu, Seoul, 08389, Republic of Korea
- Contact Name: GeumHyeon Kim
- Contact Title Lead Consultant
- E-mail Address gh.kim@dtns.co.kr
- Telephone No.: +82-2-357-8401
- Fax No.: +82-2-357-8027

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade Name	UINCARE HOME
Regulation Number	21 CFR 890.5360
Regulation Name	Measuring exercise equipment
Regulation Class	Class II
Product Code	LXJ
Product Code Name	System, Optical Position/Movement Recording

A-603, 131, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506, Republic of Korea
Tel) +82-2-6265-0944, Fax) +82-2-6265-0945

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

Contents	Primary Predicate	Reference Predicate
510(k) Number	K151446	K150462
Device Name	Recovr Rehabilitation System	Vera™
Applicant	Recovr, Inc.	Reflexion Health, Inc.
Regulation Name	Measuring exercise equipment	Measuring exercise equipment
Product Code	LXJ	LXJ
Device Class	Class II	Class II

5. Description of the Device [21 CFR 807.92(a)(4)]

The UINCARE HOME software system used with the RGB-D Camera is intended to be used to support the physical rehabilitation of adults in the clinic or at home. The system includes rehabilitation exercises for the lower and upper extremities with audio- visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

The UINCARE HOME software utilizes three off-the-shelf accessories: a motion sensing camera, a monitor and a computer; to provide physical therapists and physicians with a software system to prescribe customized physical therapy plans for patients.

UINCARE HOME software provides medical professionals the tools to record and track movements in three-dimensional space in order to identify motion and count repetitions during patient participation with a prescribed exercise. Data derived from motion tracking as well as the patient performance metrics can be reviewed by medical professionals to assess exercise movements and adherence to the prescribed exercise. The UINCARE HOME is a software tool that helps extend that expertise.

The UINCARE HOME software has three separate applications.

(1) UINCARE Client: Patient Application. This application prompts and monitors patients in the performance of a therapy prescribed by their Clinician, monitors and reports exercise data to the Clinician for analysis, and permits a Patient to communicate with that Clinician.

(2) UINCARE Manager: Clinician Application. This application allows a Clinician to define and update a patient's personal data, a patient's therapy prescription, to monitor a patient's performance of that therapy, and permits a Clinician to communicate with a patient.

(3) UINCARE Server: Cloud-based Server. It provides to communicate between the UINCARE Client and UINCARE Manager by the internet as well as to deliver and store the patient information, exercise program information and the result of exercise performed by the patient.

A-603, 131, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506, Republic of Korea
Tel) +82-2-6265-0944, Fax) +82-2-6265-0945

6. Indications for Use [21 CFR 807.92(a)(5)]

The UINCARE software system used with the RGB-D Camera is intended to be used to support the physical rehabilitation of adults in the clinic or at home. The system includes rehabilitation exercises for the lower and upper extremities with audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

7. Determination of Substantial Equivalence

The UINCARE HOME software system is substantially equivalent to legally marketed predicate devices with respect to indications for use and technology characteristics. The proposed device also has similar designs, operation mode, function and accessories with the predicate devices. The Patient Performance Metrics includes continuous ROM tracking graph of major 25 joints and the captured images of patient at designated point of each session. The performance metrics is accessible for the medical professional through the internet. The contents of performance metrics are mostly the same as the reference predicate device, but the UINCARE HOME does include the picture of patient instead of the video. However this is only an additional information to confirm the patient's exercise status. This does not raise any new issues of safety or effectiveness. Therefore, the UINCARE HOME software system is substantially equivalent to the predicate device. The below table presents the comparisons for predicate devices:

Table 1. Technological Characteristics Comparison

	Proposed Device	Primary Predicate	Reference Predicate	SE note
K Number	K172882	K151446	K150462	-
Model	UINCARE HOME	Recovr Rehabilitation System	Vera™	-
Manufacturer	UINCARE Corp.	Recovr, Inc.	Reflexion Health, Inc.	-
Indications for Use	The UINCARE software system used with the RGB-D Camera is intended to be used to support the physical rehabilitation of adults in the clinic or at home. The system includes rehabilitation exercises for the lower and upper extremities with audio-visual feedback & graphic movement representations for patients as well as	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	A software system used with the Microsoft Kinect v2 intended to support the physical rehabilitation of adults in the clinic and at home. The system includes rehabilitation exercises for the lower extremity with audio-visual feedback & graphic movement representations for patients as well as remotely accessible	Same

	Proposed Device	Primary Predicate	Reference Predicate	SE note
	remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.	approval by the medical professional are required prior to use.	patient performance video. Patient assessment, exercise guidance and approval by a medical professional is required prior to use.	
Operation Mode	Analysis Mode Rehabilitation exercise Mode Rehabilitation Game	Analysis Mode Rehabilitation exercise Mode Rehabilitation Game	Analysis Mode Rehabilitation exercise Mode Rehabilitation Game	Same
Energy Used/ Delivered	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same
Design	UINCARE HOME design requires optical motion sensing technology and computer operating system for operation.	Recovr Rehabilitation System design requires optical motion sensing technology and computer operating system for operation.	Vera™ design requires optical motion sensing technology and computer operating system for operation.	Same
Application software	Patient Application Clinician Application Server Application	Not Known	Patient Application Clinician Application Server Application	Same
Motion-Tracking Technology	Kinect camera	Kinect camera	Kinect camera	Same
Operating conditions	Windows	Not Known	Windows	Same
Accessories	1) Monitor 2) Computer 3) Microsoft Kinect Sensor camera	1) primary display monitor, secondary monitor 2) computer 3) Microsoft Kinect motion-tracking sensor	1) Monitor with touch screen 2) Computer 3) Microsoft Kinect Sensor camera	Same

A-603, 131, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506, Republic of Korea
Tel) +82-2-6265-0944, Fax) +82-2-6265-0945

Table 2. Safety Comparison

Characteristics	Proposed Device UINCARE HOME	Primary Predicate, Recovr Rehabilitation System, K151446	Reference Predicate, Vera™, K150462	SE note
Electrical Safety	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same
Mechanical Safety	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same
Thermal Safety	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same
Chemical Safety	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same
Radiation Safety	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same
Sterility	Not applicable as UINCARE HOME is a software product	Not applicable as Recovr Rehabilitation System is a software product	Not applicable as Vera™ is a software product	Same

Non-Clinical Test Summary

1) Performance Test – Range of Motion Assessment Test

Performance tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the allowable deviation.

2) Software Validation

UINCARE HOME contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance: the content of premarket submissions for software contained in medical devices, issued on May 11, 2005.

A-603, 131, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506, Republic of Korea
Tel) +82-2-6265-0944, Fax) +82-2-6265-0945

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 device.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

9. Conclusion [21 CFR 807.92(b)(3)]

The UINCARE HOME and the predicate devices are substantially equivalent in terms of intended use and performance, technology and safety. Both platforms are software systems utilizing optical position recording for physical rehabilitation exercises that use the Microsoft Kinect Sensor. 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 audiovisual 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 Sensor.