DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 30, 2015

Reflexion Health, Inc.
Huan Tran
Quality and Regulatory Manager
223 Broadway, Suite 650, San Diego, CA 92130

Re: K150462
Trade/Device Name: Vera
Regulatory Class: Unclassified
Product Code: LXJ
Dated: 9/29/2015
Received: 9/30/2015

Dear Huan Tran:

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" (21CFR 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 -S

Carlos 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)*
K150462

Device Name
Vera

Indications for Use *(Describe)*
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 patient performance video. Patient assessment, exercise guidance and approval by a 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:

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"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."

510(k) Summary

1. Owner Information

Name:	Reflexion Health, Inc.
Address:	225 West Broadway, Suite 650, San Diego, CA 92101
Phone:	619-202-4222
Fax:	None
Contact	Huan Tran
Title:	Manager, Regulatory Affairs & Quality
Email:	huan@reflexionhealth.com
Date of Preparation:	10/28/15

2. Device Information

Trade Name	Vera™
Common Name	Software system utilizing optical recording for rehabilitation exercises
Classification Name	System, optical position / movement recording
Model Number	Version 2
510(k) Submitter / Holder	Reflexion Health
510(k) Number	K150462
Predicate 510(k) Number	K130847
Device Panel	Physical Medicine
Product Code	LXJ
Classification Regulation	Unclassified

3. Description of Device

A. The main goal for the Vera™ software is to motivate patients to engage in their home physical therapy exercise program. The Reflexion Health team has done this by augmenting the “paper handouts” currently supplied to patients with purpose-built, mobile medical applications. The Vera™ 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. Vera™ software provides medical professionals the tools to record video 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 recorded video can be reviewed by medical professionals to assess exercise movements and adherence to the prescribed exercise; Vera™ is a software tool that helps extend that expertise.

The hazard analysis of the Vera™ software also indicates low risk to the end user. Pursuant to the FDA’s Guidance Document for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005), the Vera™ software level of concern is Moderate.

B. Device Components

The Vera™ software has three separate applications.

i. 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.
ii. 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.
iii. Server Application. This application provides services needed by the various applications to move the necessary data between themselves accurately and securely. It also permits an IT professional to monitor and maintain the infrastructure needed by the different applications.

C. Device Accessories

i. Motion Sensing Camera:
The Kinect Sensor from Microsoft uses structured infrared light to determine the position of objects in its field of view in three dimensions including distance, or "depth", from the camera.
ii. Microsoft Kinect Sensor Driver App v2.0
A software, provided by Microsoft, that tells the computer's operating system exactly how to work with the Microsoft Kinect Sensor.
iii. Computer (minimum configurations):
iv. Monitor with touch screen (or standard monitor with keyboard)

4. Predicate / Substantially Equivalent Device

General 510(k) Information	Predicate Device
Trade Name	Jintronix Rehabilitation System
510(k) Number	K130847
Device Panel	Physical Medicine
Product Code	LXJ
510(k) Submitter	Jintronix, Inc.

5. Intended Use

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 patient performance video. Patient assessment, exercise guidance and approval by a medical professional is required prior to use.

The device does not provide patient-specific feedback or assessment of the quality of the movement. The clinician who monitors the exercises provides the assessment.

6. Comparative Summary of Technological Characteristics

Table 1: Technological Characteristics Comparison

Characteristics	Predicate, Jintronix Rehabilitation System, K130847	Vera™	Substantial Equivalence Claim
Principles of Operation	The JRS allows a medical professional to assign movement activities to patients. JRS tracks upper extremity and trunk movement providing visual feedback of a patient movement and reports on kinematic parameters like velocity and joint angular changes during movement.	Vera™ allows medical professionals to assign movement activities to patients. Vera™ tracks rehabilitation movements providing visual feedback of a patient movement and reports on kinematic parameters like joint angular changes during movement.	Equivalent
Energy Used / Delivered	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Human Factors	No safety concern as no direct contact of JRS / Kinect with patients. JRS prescription and remote medical professional monitoring of patients allows safe home based rehabilitation exercises. JRS has been validated for accuracy / performance effectiveness both clinically and through software testing with appropriate change management and design controls. The JRS also	No safety concern as no direct contact of Vera™ / motion sensing device with patients. Vera™ prescription and remote medical professional monitoring of patients allows safe home based rehabilitation exercises. Vera™ has been validated for accuracy / performance effectiveness both clinically and through software testing with appropriate change management and design controls. The Vera™ also incorporates correction of	Equivalent

	incorporates correction of error in Kinect motion sensing to achieve optimal Kinect accuracy. Usability & Effectiveness consideration: JRS was predominantly recommended by medical professionals for the physical rehabilitation of their patients.	error in Kinect motion sensing to achieve optimal Kinect accuracy. Usability & Effectiveness consideration: Vera™ was predominantly recommended by medical professionals for the physical rehabilitation of their patients.	
Design	JRS design requires optical motion sensing technology and computer operating system with Windows for operation.	Vera™ design requires optical motion sensing technology and computer operating system for operation.	Equivalent
Materials / Technology used	JRS comprises of JRS Wave (client application software) & JRS Portal (web portal). The JRS is to be used with the Kinect for optical motion capture and a Microsoft Windows computer workstation.	Vera™ System consists of a Patient Application, Clinician Application and Server Application. The Vera™ is to be used with a motion sensing device for optical motion capture and a computer workstation.	Equivalent
Biocompatibility	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Compatibility with the environment and other devices / System Compatibility	The compatibility of JRS software with Kinect hardware and computer operating system requirements have been validated. Suitable change management and design controls have been implemented.	The compatibility of Vera™ software with Kinect hardware and computer operating system requirements have been validated. Suitable change management and design controls have been implemented.	Equivalent

Table 2: Safety Comparison

Characteristics	Predicate, Jintronix Rehabilitation System, K130847	Vera™ K150462	Substantial Equivalence Claim
Electrical Safety	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Mechanical Safety	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Thermal Safety	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Chemical Safety	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Radiation Safety	Not applicable as JRS is a software product.	Not applicable as Vera™ is a software product.	Equivalent
Sterility	JRS is a non-sterile product.	Vera™ is a non-sterile product.	Equivalent

Substantial Equivalence Conclusion:

As described under Tables 1-2 above, the Vera™ system is substantially equivalent to the predicate device in terms of intended use, principles of operation, human factors, design, materials, technology used, compatibility with the environment and / other devices, and safety. There are no differences between the Vera™ software and the predicate device and Vera™ is at least as safe and effective as the predicate.

7. Clinical Performance Data

A clinical study was performed to analyze the clinical relevance of exercises delivered by the Vera System. The study verified that physical movements delivered by Vera, executed by an individual interacting with the system, and captured by video are recognized by Clinicians to be physical rehabilitation exercises. Clinicians reviewed a series of video recordings of healthy volunteers performing rehabilitation movements to verify that the movement seen in the video is recognized as physical therapy exercise and determine if they would recommend the movement to their patients. Potential risks for their patients posed by the movements seen in the video were identified by the Clinicians.

Safety & Effectiveness Summary

The clinical study results were predominantly 100% exceeding the 95% acceptance criterion for all Vera activity movements demonstrating that the Vera movements are clinician recognized rehabilitation movements and validating the accuracy of the Vera in data processing.

Of the 230 exercises observed (10 PTs x 23 Exercises/PT), 223 (97.0%) were correctly described by the PTs.

96.7% of therapists agreed that the exercises viewed were typical of those prescribed for rehabilitation purposes and 96.7% would recommend the exercises demonstrated to appropriate patients. The data presented in this report confirm that when users perform exercises delivered by Vera, these exercises are considered rehabilitation exercises by physical therapists.

The risks that were identified by the Clinicians were classified into three categories:

Category	Potential Risks	Recommendations for Risk Mitigation
1	The exercise was determined to be unsafe if the user was using unsafe accessories such as using a chair with wheels which could compromise balance and increase risk of falling or poor form.	Recommend that clinicians advise patients on the appropriate use of ancillary equipment to promote proper balance, achieve good form and avoid risk of falling prior to and during the use of Vera.
2	The exercise was deemed unsafe to be prescribed by a physical therapist for the patient due to patient's functional ability, level of impairment, or diagnosis.	Recommend that clinicians thoroughly evaluate the patient's functional status and assign a rehabilitation program most suitable to the patients functional ability, level of impairment, and diagnosis
3	The exercise was deemed unsafe to be prescribed by a physical therapist for the patient due to patient's health history.	Prior to enrollment of a patient into a rehabilitation exercise program and the use of Vera we recommend that clinicians conduct and/or review a patient health history.

The risks identified by the clinicians are considered "universal risks" that physical therapists must consider when prescribing rehabilitation exercises to patients. Such risks are inherent in prescribing any rehabilitation exercises and it is the clinician's responsibility to evaluate a patient and prescribe exercises appropriate for the patient's health status and ability.

8. Non Clinical & Clinical Conclusions

The clinical study demonstrates that the Vera movements are medically recognized rehabilitation movements and is as safe, as effective, and performs as well or as better than the Predicate, K130847.