March 18, 2019

Penumbra, Inc.
Mary Rose
Director of Regulatory Affairs
One Penumbra Place
Alameda, California 94502

Re: K183296
   Trade/Device Name: REAL Immersive System
   Regulation Number: 21 CFR 890.5360
   Regulation Name: Measuring Exercise Equipment
   Regulatory Class: Class II
   Product Code: ISD
   Dated: February 6, 2019
   Received: February 7, 2019

Dear Mary Rose:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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
Indications for Use

The REAL Immersive System is an immersive virtual reality and display system that interactively displays and tracks upper-extremity rehabilitation exercises for adult patients using a combination of virtual environments and full presence tracked avatars for visual feedback. These rehabilitation exercises are intended to be conducted in a seated position in a clinical environment and prescribed and supervised by a medical professional trained in rehabilitation therapy.

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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I. SUBMITTER

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Contact Person: Mary Rose, Director of Regulatory Affairs
Date of Prepared: November 26, 2018

II. DEVICE

Name of Device: REAL Immersive System
Common or Usual Name: Virtual Reality based Therapy
Classification Name: Measuring Exercise Equipment
Regulatory Class: II
Product Code: ISD

III. PREDICATE DEVICE

MindMotion Pro, K162748

This predicate has not been subject to a design-related recall

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

REAL Immersive System is a digital hardware and software medical device platform using a combination of virtual environments and full presence tracked avatars for visual feedback. It is designed for use in healthcare and focusing on physical and neuro rehabilitation. The use of the device is intended to be in a clinical environment supervised by a medical professional trained in rehabilitation therapy.

REAL Immersive System contains the following components:

- All-in-One HMD with Software Application
- HMD Controller
- Wireless Transmitter Module (WTM or Large Sensor)
- Wireless Sensor Module (WSM or Small Sensor)
• Tablet with Software Application
• Sensor Charger (charging station)
• Router
• Router Battery
• Sensor Bands

V. INDICATIONS FOR USE

The REAL Immersive System is an immersive virtual reality and display system that interactively displays and tracks upper-extremity rehabilitation exercises for adult patients using a combination of virtual environments and full presence tracked avatars for visual feedback. These rehabilitation exercises are intended to be conducted in a seated position in a clinical environment and prescribed and supervised by a medical professional trained in rehabilitation therapy.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The REAL Immersive System and the predicate device MindMotion PRO, have similar technical characteristics. Both systems are software-based devices intended for a computing platform that utilizes sensors for tracking the patient’s upper extremity movements. Both systems are interactive, immersive, and translate the physical movements to moving images on the display, along with audio-visual feedback. Both systems provide the patient’s performance metrics for the healthcare professional. The subject and predicate devices are non-invasive and intended for upper extremity rehabilitation.

Principles of Operation

The MindMotion Pro is a wireless Virtual Reality (VR) rehab system utilizing optically based tracking. MindMotion is an interactive medical device that combines optically based motion capture and virtual reality technologies together with advanced cognitive principles related to body perception.
The REAL Immersive System is a wireless VR rehab system utilizing Electromagnetic (EM) tracking. The REAL Immersive system, utilizing EM tracking, is an interactive system that allows a medical professional to assign movement activities to patients. It tracks patient movement providing visual feedback and reports on kinematic parameters like joint angular changes during movement.

VII. PERFORMANCE DATA
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
The biocompatibility evaluation for the REAL Immersive System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’’ May 1, 1995, and International Standard ISO 10993-1 ‘Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,’ as recognized by FDA. The battery of testing included the following tests:

The following tests were successfully performed on the device:
- Cytotoxicity
- Irritation
- Sensitization

In summary, non-clinical testing has not found the REAL Immersive System to be biologically incompatible according to ISO 10993 requirements.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the REAL Immersive System. The system complies with the requirements of IEC 60601-1 (Ed. 3.1), IEC 60601-1-2, 60601-1-6, and IEC 62366. REAL Immersive System also underwent FCC testing and is FCC certified.

Software Verification and Validation Testing
Software verification and validation testing and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level of concern. Prior to mitigation of hazards, there is a small but non-zero risk of Minor injury to the user.

Bench-Top Performance (Design Verification)

Design Verification testing was conducted to evaluate the physical and mechanical properties and to demonstrate substantial equivalence to the predicate device. The tests were performed included; Packaging, Battery performance, HMD and Sensor Accuracy, Simulated Use, and Usability Interface Summative.

All tests passed successfully.

Animal Studies

No Animal study was conducted as bench testing was determined sufficient for verification and validation purposes.

Clinical Studies

No clinical study was conducted as bench testing was determined sufficient for verification and validation purposes. A review was conducted considering published clinical study articles that featured devices with similar intended use. The literature review was used to support the proposed indications for use by leveraging clinical outcomes from devices that are considered technologically similar.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the REAL Immersive System should perform as intended in the specified use conditions.

The subject REAL Immersive System is substantially equivalent to the predicate device MindMotion Pro. The subject device has the same intended use as the predicate device. The subject and the predicate devices differ slightly in regards to technological variations, while maintaining the same fundamental scientific technology. However, these differences do not raise different questions of safety and effectiveness.
The device testing described in the 510(k) Summary demonstrate the subject devices are substantially equivalent to the predicate device in regards to operating principle, fundamental technology, and device performance.