



November 16, 2021

AppliedVR, Inc.
Jafar Shenasa
Vice President, Regulatory Affairs and Quality Assurance
16760 Stagg St, Ste 216
Van Nuys, California 91406

Re: DEN210014

Trade/Device Name: EaseVRx
Regulation Number: 21 CFR 890.5800
Regulation Name: Virtual reality behavioral therapy device for pain relief
Regulatory Class: Class II
Product Code: QRA
Dated: March 30, 2021
Received: March 30, 2021

Dear Jafar Shenasa:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the EaseVRx, a prescription device under 21 CFR Part 801.109 with the following indications for use:

EaseVRx is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients (age 18 and older) with a diagnosis of chronic lower back-pain (defined as moderate to severe pain lasting longer than three months). The device is intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the EaseVRx, and substantially equivalent devices of this generic type, into Class II under the generic name Virtual reality behavioral therapy device for pain relief.

FDA identifies this generic type of device as:

Virtual reality behavioral therapy device for pain relief. A virtual reality behavioral therapy device for pain relief is a device intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display which utilizes a software program containing the behavioral therapy content.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 30, 2021, FDA received your De Novo requesting classification of the EaseVRx. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the EaseVRx into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the EaseVRx can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are adverse tissue reaction, electric shock, nausea and motion sickness, discomfort, ineffective treatment, and use error or improper device use. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Electric shock or burn or interference with other devices	Electromagnetic compatibility (EMC) testing Electrical, mechanical, and thermal safety testing
Nausea and motion sickness	Clinical performance testing Labeling
Discomfort	Clinical performance testing Labeling
Ineffective treatment	Clinical performance testing Software verification, validation, and hazard Analysis Labeling
Use error or improper device use leading to a delay in treatment	Labeling

In combination with the general controls of the FD&C Act, the virtual reality behavioral therapy device for pain relief is subject to the following special controls:

Special Controls

- (1) Clinical performance testing under the labeled conditions for use must validate the model of behavioral therapy as implemented by the device and evaluate all adverse events.
- (2) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (3) Software verification, validation, and hazard analysis must be performed.
- (4) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.
- (5) Labeling must include the following:
 - (i) A warning regarding the risk of nausea and motion sickness
 - (ii) A warning regarding the risk of discomfort from the device
 - (iii) A summary of the clinical testing with the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Virtual reality behavioral therapy device for pain relief they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Kaitlin Olsen at Kaitlin.Olsen@fda.hhs.gov.

Sincerely,

Christopher Loftus, M.D.
Acting Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health