December 4, 2024

AppliedVR
Michael Chibbaro
Vice President, Quality Affairs and Regulatory Affairs
16760 Stagg St
Van Nuys, California 91406

Re: K243417
Trade/Device Name: RelieVRx
Regulation Number: 21 CFR 890.5800
Regulation Name: Virtual reality behavioral therapy device for pain relief
Regulatory Class: Class II
Product Code: QRA
Dated: October 31, 2024
Received: November 4, 2024

Dear Michael Chibbaro:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243417

Device Name
RelieVRx

Indications for Use *(Describe)*
RelieVRx 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.

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.

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510(k) SUMMARY – K243417

Manufacturer/Submitter:	AppliedVR 16760 Stagg St Van Nuys, CA, 91406 Phone: (844) 857-0010
Contact:	Michael Chibbaro Vice President, QA/RA Phone: (408) 718-5657 Email: mchibbaro@appliedvr.io

Date Prepared:	December 4, 2024
Device Trade Name:	RelieVRx
Regulation and Classification Description:	21 CFR 890.5800, Virtual reality behavioral therapy device for pain relief
Class:	II
Product Code:	QRA
Predicate Device:	EaseVRx (DEN210014)

Indications for Use

RelieVRx 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.

Device Description

RelieVRx is an immersive virtual reality (VR) system with preloaded software content on a proprietary hardware platform that delivers automated cognitive behavioral therapy (CBT) and other behavioral methods to patients diagnosed with chronic lower back-pain (defined as moderate to severe pain lasting longer than three months). The VR content is delivered while incorporating CBT to enable diaphragmatic breathing exercises and mindfulness strategies, and is intended to be self-administered, unsupervised in the patient's home while the patient is in a seated position. Each device is intended for single patient use during treatment and can be used on multiple patients over the device lifetime. The medical device does not include non-medical software and is only effective when treating chronic lower back pain.

Similar to the predicate device, EaseVRx (DEN210014), the RelieVRx device consists of an off-the-shelf VR head-mounted display with added Breathing Amplifier and AppliedVR developed software. The Breathing Amplifier is a mechanical attachment added to the commercially available headset which enables diaphragmatic breathing exercises designed to enhance the user's engagement by amplifying the user's exhalation into the on-board microphone. No change is being made to the core RelieVRx program used in the pivotal clinical trial conducted for market authorization; the 8-week theme-based structure, weekly VR-experience structure, and daily session structure is unchanged. Minor changes were made to the content of

the 56 VR sessions. Briefly, 46 of 56 VR sessions are unchanged. Of the 10 sessions that have been updated, there were 3 changes to Relaxation/Interoceptive sessions, and 7 changes to Distraction sessions. The 3 Relaxation/Interoceptive sessions include slightly altered minor graphical rendering to improve images. The 7 changes to Distraction sessions include changed background which is dimmer to help to user to achieve the goal of attentional focus (dragonfly). There is no negative impact on safety or effectiveness.

Principles of Operation

Similar to the predicate device, EaseVRx (DEN210014), RelieVRx is designed to scaffold learning of pain relief skills by delivering therapeutic principles in VR through an 8-week, 56-day program. Each of the 56 VR sessions is 2-16 minutes in length (average of 6 minutes). The content and associated scripts are structured in a logical sequence such that informational content (cognitive) is delivered in conjunction with experiential content (behavioral), allowing the user to become educated and skilled in the techniques necessary to mitigate their pain.

Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject and Predicate Devices

	RelieVRx (K243417, Subject device)	**EaseVRx (DEN210014, Predicate device)**
Regulation/ Product Code	21 CFR 890.5800 (Virtual reality behavioral therapy device for pain relief) QRA (Virtual Reality Behavioral Therapy Device For Pain Relief)	21 CFR 890.5800 (Virtual reality behavioral therapy device for pain relief) QRA (Virtual Reality Behavioral Therapy Device For Pain Relief)
Indications for Use	RelieVRx is a prescription-use immersive virtual reality system indicated 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.	EaseVRx is a prescription-use immersive virtual reality system indicated 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.
Head-Mounted Device (HMD) Specifications		
HMD Manufacturer and Model Number:	GoerTek Technology Inc. Model: A7Q10/Pico G3	GoerTek Technology Inc. Model: A7510/Pico G2 4K
HMD Reference Number	RVX-3001	Not publicly available
Rating:	5VDC 3.0A and 9VDC 3A	5V DC, 2A
Screen Resolution	3664 x 1920	3840 x 2160

	RelieVRx (K243417, Subject device)	**EaseVRx (DEN210014, Predicate device)**
Number of Pixels Per Eye (horizontal / vertical):	1832 x 1920	1907 x 1964
Field of View Per Eye (horizontal / vertical):	98 / 98	98 / 101
Luminance (Minimum and maximum)	20nit and 90nit	0.06nit and 64.7nits
CPU:	Qualcomm XR2	Not publicly available
Weight:	380g (w/o Band), 604g (total)	278g (w/o Band), 470g (total)
Frame-Rate:	90 fps	72 fps
Minimum Frame-Rate Using the Software:	60 fps	Not publicly available
Interpupillary Distance (IPD) and IPD Range:	Default 63mm, adjustable range from 58mm - 69mm	Default 63mm, optical adaptive range is from 55~71mm
Range in Depths of the Virtual Content in the Software:	2m for optics; 3m for launcher software	2m for optics; 3m for launcher software
Eye Relief for Prescription Lenses:	17mm	17mm
Storage:	128GB	Not publicly available
Tracking degree of headset x/y/z 360°:	3 Degrees of Freedom (3DoF)	3 Degrees of Freedom (3DoF)
Number of Discharge Cycles:	500	Not publicly available
Expected Service Life of the ME Equipment:	3 year	Not publicly available
Type BF applied parts	Type BF applied parts	Not publicly available
Technical Specification of USB-C Charger:	I/P: 100 – 240 Vac, 50/60Hz, 0.6A, Class II O/P 3.6-6V DC, 3A; 6-9V DC, 2A; 9-12V DC, 1.5A I/P: 100 – 240 Vac, 50/60Hz, 0.5A, Class II O/P 5V DC, 3A; 9V DC, 2A; 12V DC, 1.5A I/P: 110 – 240 Vac, 50/60Hz, 0.6A, Class II O/P 5V DC, 3A; 9V DC, 2A; 12V DC, 1.5A	Not publicly available

	RelieVRx (K243417, Subject device)	EaseVRx (DEN210014, Predicate device)
Frequency Range (Bluetooth):	2400-2483.5 MHz	Not publicly available
Max Output Power (Bluetooth)	10 mW	Not publicly available
Frequency Range (WiFi):	2400 - 2483.5 MHz, 5150 - 5350 MHz Indoor use only, 5470 - 5725 MHz	Not publicly available
Max Output Power (WiFi):	100 mW	Not publicly available
Prescription or OTC	Prescription	Prescription
Energy Source	Rechargeable lithium battery through a USB power supply port.	Rechargeable lithium battery through a USB power supply port.

The indication for use (IFU) statements of the subject and the predicate devices are identical. The differences in technological characteristics are as follows:

- The RelieVRx (RVX-3001) uses a new head mounted device (Pico G3 VR HMD) whereas the predicate device uses the Pico G2 4K VR head mounted device.
- The RelieVRx (RVX-3001) contains a new user interface for the home screen.
- The RelieVRx (RVX-3001) contains updates to onboarding sequence to include reorientation and IPD (inter pupillary distance) adjustment.
- The RelieVRx (RVX-3001) changed its reorientation functionality from long press to short press.
- The RelieVRx (RVX-3001) contains visual enhancements and other minor adjustments such as: Hocus Focus environment update, onboarding timing and SFX adjustments, skip confirmation modal, analytics improvements, and session pause while in-app menu is active for quality-of-life updates.
- The RelieVRx (RVX-3001) contains bug fixes that were not present in EaseVRx.

Non-clinical Performance Testing

The following nonclinical performance testing was conducted to demonstrate substantial equivalence.

Electromagnetic Compatibility and Electrical Safety

RelieVRx was tested according to the following FDA-recognized consensus standards:

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, "Medical Electrical Equipment; Part 1: General requirements for basic safety and essential performance." Results demonstrated that the device is compliant to this standard.
- IEC 60601-1-2: Edition 4.1 (2020), "Medical Electrical Equipment -Part 1-2: General Requirements for Basic Safety and Essential Performance-Collateral Standard: Electromagnetic disturbances - Requirements and Tests."
- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, "Medical electrical equipment: General requirements for basic safety and essential performance -Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare

environment."

Biocompatibility

Same as the predicate device, EaseVRx (DEN210014), device components that come in contact with the patient during use include: the Pico G3 headset face pad (Polyurethane or PU), straps (Silicone, PU, Polyethylene Terephthalate or PET, Polyurethane Fabric or Spandex, and Polyamides or Nylon), battery compartment (PU) and controller (Polycarbonate or PC, Acrylonitrile Butadiene Styrene or ABS). These components are considered surface medical device components with intact skin contact, for a cumulative limited contact duration (<24 hours) per Annex A of ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Based on the contact type and contact duration, according to Attachment G: "Biocompatibility of Certain Devices in Contact with Intact Skin" of FDA's Guidance for Industry and Food and Drug Administration Staff - Use of International ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued September 8, 2023), all patient contacting materials of RelieVRx are listed in Section B of Attachment G and therefore, these materials have a history of safe use in medical devices. Additionally, considering the total cumulative contact duration is low, the risk associated with cytotoxicity, irritation, and sensitization are low. Thus, biocompatibility data was not evaluated for RelieVRx. Biocompatibility risks are addressed through reliance on relevant quality system requirements and postmarket controls related to:

- Purchasing controls (21 CFR 820.50) of device materials
- Production and process controls (21 CFR 820.70) for manufacturing materials
- Acceptance activities (21 CFR 820.80) for component and manufacturing materials
- Corrective and preventive action (21 CFR 820.100)
- Complaint files (21 CFR 820.198)
- Medical device reporting (MDR) (21 CFR 803)

Software and Cybersecurity

AppliedVR provided documentation acceptable for software and firmware with a "Basic" Level of Documentation, as outlined in the FDA guidance document "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff" issued on June 14, 2023. The primary risk to patients is needing to revert to standard of care due to software/firmware malfunction or failure. Adequate documentation describing the software, firmware, software requirements specification, traceability, and revision level history provides the foundation that the software will operate in a manner as described in the specifications. A hazard analysis was performed to characterize software risks including device malfunction and measurement related errors. The submission included verification and validation (V & V) testing to address the potential hazards with satisfactory results.

Cybersecurity was assessed and documented according to the FDA Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" dated September 27, 2023.

Sterilization and Reprocessing

RelieVRx is not provided sterile. The device is intended for repeat use for a single user. Cleaning instructions are included in the User Manual.

Shelf Life and Packaging

RelieVRx does not have a specific shelf-life.

Clinical Testing

Substantial equivalence of the subject device to the predicate has been established through the results of nonclinical testing.

Conclusion

The subject device RelieVRx has the same intended use, indications for use, and principles of operation, and highly similar technological characteristics as the predicate device. The technological differences identified do not raise new questions of safety or effectiveness compared to the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.