August 13, 2025

AppliedVR
Gabriela Pastushenko
Director of Regulatory Affairs & Quality Affairs
16760 Stagg St
Van Nuys, California 91406

Re: K251519
Trade/Device Name: RelieVRx (Pico G3)
Regulation Number: 21 CFR 890.5800
Regulation Name: Virtual Reality Behavioral Therapy Device For Pain Relief
Regulatory Class: Class II
Product Code: QRA
Dated: May 15, 2025
Received: May 16, 2025

Dear Gabriela Pastushenko:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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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)*
K251519

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

Manufacturer/Sponsor:	AppliedVR 16760 Stagg St Van Nuys, CA, 91406 Phone: (844) 857-0010
Contact:	Gabriela Pastushenko Director of Regulatory Affairs & Quality Affairs 562-659-5650 gpastushenko@appliedvr.io

Date Prepared:	August 12, 2025
Device Trade Name:	RelieVRx
Common/Usual Name:	Virtual Reality Behavioral Therapy Device For Pain Relief
Classification:	21 CFR 890.5800, Virtual reality behavioral therapy device for pain relief.
Class:	II
Product Code:	QRA
Predicate Device:	RelieVRx (K243417)

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 pain. 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. The device is powered by a rechargeable lithium battery. Each device is intended for a single patient. The medical device is meant for repeated use, does not include non-medical software, and is only effective when treating chronic pain.

This 510(k) was submitted to add a predetermined change control plan to support future potential modifications to the device hardware.

Principles of Operation
The scientific basis for the device is from evidence-based behavioral treatments for pain, including CBT, Mindfulness-Based Stress Reduction (MBSR), Acceptance and Commitment Therapy (ACT), compassion

training, and pain neuroscience education. CBT for chronic pain is based on the premise that pain-related distress can be maintained or exacerbated by behavioral and cognitive factors. The goal of this treatment is to change these unhelpful factors with the intent of reducing symptoms, improving function, and supporting rehabilitation. The VR component's basis stems from VR's unique capabilities to alter the user's senses, amongst which is the perception of pain.

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

The predicate device in the current 510(k) is the manufacturer's own legally marketed predicate device cleared under K243417. The predicate and subject devices share the same intended use and technological characteristics as shown in Table 1.

Table 1: Comparison of Subject and Predicate Devices

	RelieVRx (Subject device)	**RelieVRx K243417 (Primary Predicate device)**	**Discussion of Differences**
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	Same
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.	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.	Same
Manufacturer and Model of Headset	GoerTek Technology Inc. Model: A7Q10/Pico G3	GoerTek Technology Inc. Model: A7Q10/Pico G3	Same
REF Number	RVX-3001	RVX-3001	Same

	RelieVRx (Subject device)	RelieVRx K243417 (Primary Predicate device)	Discussion of Differences
Rating	5V, 3A	5V, 3A	Same
Screen Resolution	3664 x 1920	3664 x 1920	Same
Number of Pixels Per Eye (horizontal / vertical):	1832x1920	1832x1920	Same
Field of View Per Eye (horizontal / vertical):	98 / 98	98 / 98	Same
Luminance: (Maximum and minimum)	20nit and 90nit	20nit and 90nit	Same
CPU:	Qualcomm XR2	Qualcomm XR2	Same
Weight:	380g (w/o Band), 604g(total)	380g (w/o Band), 604g(total)	Same
Frame-Rate:	90 fps	90 fps	Same
Minimum Frame-Rate Using the Software:	60 fps	60 fps	Same
Interpupillary Distance (IPD) and IPD Range:	Default 63mm, adjustable range from 58mm - 69mm	Default 63mm, adjustable range from 58mm - 69mm	Same
Range in Depths of the Virtual Content in the Software:	2m for optics; 3m for launcher software	2m for optics; 3m for launcher software	Same
Eye Relief for Prescription Lenses:	17mm	17mm	Same
Storage:	128GB	128GB	Same
Tracking degree of headset x/y/z 360°:	3 Degrees of Freedom (3DoF)	3 Degrees of Freedom (3DoF)	Same
Number of Discharge Cycles:	500	500	Same
Expected Service Life of the ME Equipment:	3 year	3 year	Same
Type BF applied parts	Type BF applied parts	Type BF applied parts	Same

	RelieVRx (Subject device)	RelieVRx K243417 (Primary Predicate device)	Discussion of Differences
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	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	Same
Frequency Range (Bluetooth):	2400-2483.5 MHz	2400-2483.5 MHz	Same
Max Output Power (Bluetooth)	10 mW	10 mW	Same
Frequency Range (WiFi):	2400 - 2483.5 MHz, 5150 - 5350 MHz Indoor use only, 5470 - 5725 MHz	2400 - 2483.5 MHz, 5150 - 5350 MHz Indoor use only, 5470 - 5725 MHz	Same
Max Output Power (WiFi):	100 mW	100 mW	Same
Prescription or OTC	Prescription	Prescription	Same
Energy Source	Rechargeable lithium battery through a USB power supply port.	Rechargeable lithium battery through a USB power supply port.	Same

Nonclinical Performance Testing

No new nonclinical performance testing was conducted to demonstrate substantial equivalence. The only changes that have been made to the RelieVRx in the current submission are the addition of a Predetermined Change Control Plan to accommodate potential future updates to the device hardware. Please refer to K243417 for a comprehensive description of non-clinical testing that has been completed to validate the device.

Predetermined Change Control Plan (PCCP)

This 510(k) includes a Predetermined Change Control Plan (PCCP), which defines a structured, risk-based protocol to implement future hardware platform changes for the RelieVRx device without altering its intended use or therapeutic content.

a. Planned Modifications:

The PCCP supports a defined update from the currently supported head-mounted display (HMD) to a new VR headset with equivalent or improved specifications. Modifications covered include hardware integration, necessary software updates to maintain compatibility (e.g., firmware, SDK, UI), and Breathing Amplifier changes where needed.

b. Testing Methods:

All changes implemented under the PCCP will follow the verification and validation protocols outlined in AppliedVR's Quality System. This includes electrical and mechanical testing (IEC 60601-1/11), electromagnetic compatibility (IEC 60601-1-2), environmental and acoustic safety, and performance benchmarking against target hardware specifications.

c. Validation Activities and Performance Requirements:

Software validation includes regression, integration, compatibility, performance, and cybersecurity testing. Breathing Amplifier compatibility is evaluated through mechanical and functional assessments with fallback plans for redesign, if necessary. All modified configurations must meet predefined acceptance criteria—aligned with Table 6 of the PCCP—for safety, biocompatibility, and software performance.

d. User Communication and Labeling Updates:

Authorized changes under the PCCP will be clearly communicated to users through updated labeling, onboarding materials, and device instructions in accordance with 21 CFR 801.5. These updates will reflect any changes in device setup, use, or interaction resulting from the hardware modification.

Conclusion

The subject device RelieVRx has identical intended use, indications for use, principles of operation, and technological characteristics as the predicate device. The addition of the predetermined change control plan does not raise new questions of safety or effectiveness between the subject and predicate devices.