April 10, 2026

Cognifisense, Inc.
Amanda Way
CEO & President
1271 Lakeside Drive, Apt. 3121
Sunnyvale, California 94085

Re: K254004
Trade/Device Name: VRNT
Regulation Number: 21 CFR 890.5800
Regulation Name: Virtual reality behavioral therapy device for pain relief
Regulatory Class: Class II
Product Code: QRA
Dated: January 9, 2026
Received: January 9, 2026

Dear Amanda Way:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

CHUN XU -S

For Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254004

Device Name
VRNT

Indications for Use *(Describe)*
VRNT 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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Date Prepared: **April 10, 2026**

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Contract:
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Device Information:

Trade Name:	VRNT
Classification Name:	Virtual reality behavioral therapy device for pain relief
Device Class:	II
Product Code:	QRA
Regulation Number:	21 CFR 890.5800
Panel:	Neurology

Predicate Device: VRNT (K230814)

Reason for submission: Device Modification

Device Description

VRNT is an immersive virtual reality (VR) system which delivers behavioral therapy content for the treatment of chronic pain via virtual reality hardware. VRNT is a prescription-use device containing pre-loaded, proprietary content on commercially available VR hardware. The behavioral content incorporates cognitive behavioral therapy (CBT) skills and other evidence-based behavioral methods.

VRNT is designed to be used in an 8-week treatment program which delivers a multifaceted combination of pain management skills training through a sequence of daily sessions (5 days a week) ranging from 7-27 minutes in length (average of 20 minutes). Similar to multisession behavioral treatments, the treatment program begins with basic skills and progresses to more advanced skills over the 8 weeks. Initial themes in VRNT are focused on understanding the basic science behind chronic pain and developing rudimentary breathing, bodily awareness and mindfulness, relaxation and interoception skills. Later themes build on these skills; they expand on interoception, add passive distraction and refocusing attention, thought appraisal skills, as well as skills for managing emotion triggers. Finally, the program provides opportunities to practice applying the education and self-regulation skills when faced with actual pain triggers. The treatment content, thus, allows the patient over time to build upon education, skills training and their own experiential learning in a manner that increasingly mimics real-world situations.

Indications for Use:

VRNT 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.

Comparison of Technological Characteristics with the Predicate Device

The subject device, VRNT (ver 2.5), is substantially equivalent to the predicate device (VRNT ver 2.24) cleared under K230814. The indication for use (IFU) statements of the subject and the predicate devices are identical.
The devices are intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain. The devices also are equivalent in their technological principles of operation, in that both administer therapy via a virtual reality system which utilizes a software program containing content that targets behavior change based on substantially similar principles; specifically, cognitive behavioral therapy (CBT) and other evidence-based behavioral methods. Finally, the virtual reality hardware used by the two systems has performance specifications that are substantially equivalent for the given type of application. i.e., therapy program.

The modified device is unchanged since the K230814 predicate device, except for the Virtual Reality (VR) headset. The modified device uses VR Headset Meta Quest, whereas the predicate device uses Samsung Gear VRx.

Table 1. Substantial Equivalence Summary Table

Criteria	VRNT (Ver 2.24, Predicate Device)	VRNT (Ver 2.5, Subject Device)	Comment
Classification/ Product Code	890.5800 QRA Virtual Reality Behavioral Therapy Device for Pain Relief	890.5800 QRA Virtual Reality Behavioral Therapy Device for Pain Relief	The same
Physical State	Virtual reality display, software	Virtual reality display, software	The same
Technical Method	Uses a virtual reality display to provide behavioral-based treatment to patients with chronic pain by modifying the patient's thinking and behavioral patterns	Uses a virtual reality display to provide behavioral-based treatment to patients with chronic pain by modifying the patient's thinking and behavioral patterns	The same
Target Area	Areas of pain (lower back pain)	Areas of pain (lower back pain)	The same
Intended Use	Virtual reality behavioral therapy device for chronic lower back pain relief	Virtual reality behavioral therapy device for chronic lower back pain relief	The same
Indications for use	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.	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.	The same
Technological characteristics	Virtual reality display (i.e., hardware): Samsung GearVR Headset + Controller + Samsung Galaxy S9	Virtual reality display (i.e., hardware): Meta Quest 3s	Different. The subject and predicate devices use different

	HTC Vive + VR-ready PC (used only in Onboarding) Parameters: Not publicly available.	HTC Vive + VR-ready PC (used only in Onboarding) Parameters (Meta Quest 3S): **Display / Resolution:** Dual LCD displays 2064 × 2208 pixels per eye. **Field of View (FOV):** ~110° horizontal, 96° vertical (wide immersive view) **Interpupillary Distance (IPD) Adjustment:** Mechanical continuous slider from ~53–75 mm for precise fit **Degrees of Freedom (DOF):** 6 DoF headset + controllers; supports inside-out tracking (positional + orientation) **Optics / Lenses:** Advanced pancake lenses for slimmer optics and improved clarity across edges **Tracking Method:** Inside-out optical tracking using multiple cameras + IMU (no external sensors) **Refresh Rate:** 72, 90, 120 Hz	hardware, but each hardware set provides the same level of functionality, salient performance, and level of immersion necessary for VRNT. The ability to view all contents, progress through all screens and components of the therapy as well as the ability to interact with all elements of the user interface were thoroughly evaluated as part of the V&V testing. The same specifications and acceptance criteria, and verification methods were used for both the modified and predicate versions.
Therapy Approach and dosage	VRNT is an 8-week program, 5 days / week, totaling 40 sessions, each lasting 7-27 minutes (20-minute average) Optional additional sessions.	VRNT is an 8-week program, 5 days / week, totaling 40 sessions, each lasting 7-27 minutes (20-minute average) Optional additional sessions	Same
VR Therapy content	Treatment content includes: • Pain Education • Relaxation/interoception • Mindful escapes and Attention (re)focusing • Diaphragmatic breathing • Graded exposure therapy • Practicing self-regulatory techniques when facing pain triggers	Treatment content includes: • Pain Education • Relaxation/interoception • Mindful escapes and Attention (re)focusing • Diaphragmatic breathing • Graded exposure therapy • Practicing self-regulatory techniques when facing pain triggers	Same

Performance Data.

Performance data including Software verification, validation, hazard analysis, and compliance with special controls supporting substantial equivalence and addressing the differences of the VR hardware.

CognifiSense's VRNT device was subjected to design verification and design validation activities utilizing various methods and techniques. The software was inspected, reviewed and tested by multiple individuals to demonstrate that the device modifications meet all the functional and performance requirements defined in the Software Requirements Specifications (SRS) and Software Development Specifications (SDS), and to ensure that all control measures identified during risk management activities have been properly implemented and are as effective as the predicate device.

Risk Management activities were conducted in accordance with ISO 14971 to assure that all risk related to use of VRNT, including use related risks and cybersecurity risks, are appropriately controlled. All control measures were verified and found to be as effective as the predicate device.

Tasks completed to verify device software safety and performance include:

- Comprehensive end-to-end assessment of all functional requirements and software operation. This testing also verifies the ability to view all contents, progress through all screens and components of the therapy as well as the ability to interact with all elements of the user interface to address hardware differences. The same specifications and acceptance criteria, and verification methods were used for both the modified and predicate versions.
- Risk Management lifecycle activities performed in accordance with ISO 14971.
- Anomaly Reporting and Resolution (analysis and disposition of unresolved issues).
- Traceability Analysis (tracing software requirements and risk control measures to the verification and validation testing as part of the Design Control process).
- Software Documentation: submission contains documentation for software with Basic Documentation level, as outlined in the FDA guidance document. Documentation includes software description, software requirements specification, traceability, revision level history, and cybersecurity providing 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.

Clinical Testing

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

Substantial Equivalence Conclusion

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