October 31, 2023

CognifiSense, Inc.
Tassilo Baeuerle
President & CEO
1271 Lakeside Drive, Suite 3121
Sunnyvale, California 94085

Re: K230814
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: March 23, 2023
Received: March 24, 2023

Dear Tassilo Baeuerle:

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.

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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230814

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.

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.

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Date Prepared: October 31, 2023

Submitter Information:

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Device Information:

Trade Name:	VRNT
Classification Name:	Virtual Reality behavioral therapy device for pain relief
Device Classification:	Class II
Product Code:	QRA
Regulation Number:	21 CFR 890.5800
510(k) Number:	K230814
Panel:	Neurology

Predicate Device: EaseVRx by AppliedVR, Inc., DEN210014

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 shown in the figure below. The behavioral content incorporates cognitive behavioral therapy (CBT) skills and other evidence-based behavioral methods.

VRNT uses a virtual reality system called GearVR, consisting of a virtual reality head-mounted display, a hand controller and a smartphone

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, is substantially equivalent to the predicate device (EaseVRx) cleared under DEN210014. Both devices have the same intended use - a prescription-use immersive virtual reality system intended to provide adjunctive treatment 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 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 main differences between the new device and the predicate are:

1. Behavioral Therapy Content:
    a. VRNT uses different implementation of the same / similar cognitive behavioral and other evidence-based behavioral methods, e.g., VRNT uses a different audiovisual representations / approach for the same / similar behavioral methods.
    b. VRNT provides additional content to have the patient practice applying the skills when faced by common pain triggers.

2. Virtual Reality (VR) Hardware: Use of different VR hardware systems (hardware performance is equivalent

for its application, i.e., therapy program).

Table 5-1. Substantial Equivalence Summary Table

Criteria	EaseVRx (DEN210014)	VRNT	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	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.	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.	The same Disease (CLBP), population, clinical context and setting (home use) are the same
Technological characteristics	Virtual reality display (i.e., hardware): Pico G2 4K VR Headset + Controller	Virtual reality display (i.e., hardware): Samsung GearVR Headset + Controller + Samsung Galaxy S9 (used in actual therapy) HTC Vive + VR-ready PC (used only in Onboarding)	Equivalent. The subject and predicate devices use different hardware, but each hardware set provides the same level of functionality, salient performance, and level of immersion necessary for VRNT.
Therapy Approach and dosage	EaseVRx is an 8-week program, 7 days / week, totaling 56 daily sessions, each lasting 2-16 minutes (6-minute average). Optional on-demand library.	VRNT is an 8-week program, 5 days / week, totaling 40 sessions, each lasting 7-27 minutes (20-minute average) Optional additional sessions	Equivalent. Overall, the therapy duration is the same, but the length, frequency and content of the sessions differs.
VR Therapy content	Treatment content includes: • Pain education • Relaxation/interoception • Mindful escapes and Pain distraction games • Dynamic breathing	Treatment content includes: • Pain Education • Relaxation/interoception • Mindful escapes and Attention (re)focusing • Diaphragmatic breathing • Graded exposure therapy	Equivalent. Both therapies provide a common pain education. Both teach self-regulation skills around reducing physical and mental

		• Practicing self-regulatory techniques when facing pain triggers	arousal. VRNT adds the presentation of commonly recognized pain triggers so that patients can practice applying the education and self-regulation skills when confronted with these triggers.

Performance Data.

VRNT is designed in conformance with the following FDA recognized consensus standards:

- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
- IEC 62304:2006/AMD 1:2015 – Medical Device Software – Software Life-Cycle Processes

CognifiSense's VNRT 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 meets the functional and performance requirements defined in the Software Requirement 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 effective.

Tasks completed to validate device software safety and performance include:

- Comprehensive end-to-end assessment of all functional requirements and software operation;
- Code inspections, walkthroughs and reviews;
- Technical design, milestone, and document reviews;
- Risk Management activities (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).

Software verification and validation evaluations were conducted, and documentation was provided as recommended by FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The VRNT is considered a "minor" level of concern; the primary risk to patients is delay of treatment due to software/firmware malfunction or failure.

CognifiSense believes that the aforementioned non-clinical testing demonstrates that the VRNT is designed in such a way that, when used in accordance with its indications for use and labeling, the safety and effectiveness, as well as the performance characteristics of the subject device are substantially equivalent to the predicate device.

Risk Management:

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 effective. All individual and overall residual risk is acceptable. The new device has virtually the same safety characteristics as the predicate device and same risk profile.

SUMMARY OF CLINICAL INFORMATION

VRNT was evaluated in a prospective, 2-arm, usual care/waitlist-controlled, randomized clinical trial.

In 2 arm waitlist-controlled trials, the patients randomized to the treatment group receive immediate treatment whereas individual randomized to the control group wait a fixed amount of time before intervention is initiated. The primary objective of this clinical trial was to assess the effectiveness of VRNT program in patients with chronic back pain (cBP).

The trial sample was 61 adults with cBP. There were two pre-determined primary effectiveness outcomes: pain intensity and pain interference, assessed with the Short-Form Brief Pain Inventory (BPI-SF). Intent-to-treat analyses indicated that the VRNT condition had significantly greater reduction in pain intensity at post- treatment than controls (group by time interaction, $p = 0.014$, $g = 0.63$; medium to large effect); 60% of VRNT participants, compared to 30% of controls, achieved clinically meaningful reductions (at least 30%) in pain intensity ($p = 0.019$), and 47% of VRNT participants compared to 13% of controls achieved ≥50% pain reduction ($p = 0.005$). The VRNT condition also had significantly greater reduction in pain interference at post-treatment than controls (group by time interaction, $p = 0.002$, $g = 0.84$; large effect); 77% of VRNT participants compared to 53% of controls achieved at least 30% reduction in interference ($p = 0.058$), and 60% of VRNT participants compared to 30% of controls achieved ≥50% pain interference reduction ($p = 0.019$). The treatment effect on both primary outcomes continued to improve at 2-week follow-up (slightly larger between-condition effect sizes on both primary outcomes).

Analysis of individual items in the pain interference scale also showed significantly greater improvement in the VRNT condition than the controls in interference with general activity, mood, and sleep (group by time interaction p values: 0.03, 0.0006, 0.001, respectively). With respect to interference with general activity 80% of VRNT participants and 53% of control participants achieved ≥30% reduction, and 67% of the VRNT participants achieved ≥50% reduction, compared to 37% in the control group. For pain interference with mood, 77% of VRNT participants and 37% of control participants achieved ≥30% reduction, and 63% of the VRNT participants achieved ≥50% reduction. For pain interference with sleep, 73% of VRNT participants and 30% of control participants achieved ≥30% reduction, and 53% of the VRNT participants achieved ≥50% reduction. 3% (1/31) of VRNT condition participants reported any adverse events (temporary cybersickness). In conclusion, VRNT was statistically and clinically superior in reducing pain intensity and interference compared to the control condition.

Substantial Equivalence Conclusion

VRNT has the same intended use and performance characteristics as the predicate device. Based on the performance data and software verification and validation testing, it can be concluded that the differences in technological characteristics between the VRNT and the predicate device do not raise different questions of safety and effectiveness. The indications for use, technological characteristics, and performance characteristics for the VRNT are assessed to be substantially equivalent to those of the predicate device.