OculoMotor Technologies
% Allison Komiyama, Ph.D., RAC
VP, MedTech Innovation
RQM+
2251 San Diego Ave., Suite B-257
San Diego, California 92110

Re: K232930
Trade/Device Name: VERVE
Regulation Number: 21 CFR 886.1290
Regulation Name: Fixation Device
Regulatory Class: Class I
Product Code: SBN
Dated: May 7, 2024
Received: May 7, 2024

Dear Allison Komiyama, Ph.D., RAC:

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K232930

Device Name
VERVE

Indications for Use *(Describe)*
VERVE is indicated for the treatment for convergence insufficiency in patients aged 11-35 under the supervision of a medical professional by providing therapeutic visual procedures in a virtual reality setting.

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
K232930

DATE PREPARED
June 11, 2024

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DEVICE INFORMATION

Proprietary Name/Trade Name:	VERVE
Common Name:	Fixation Device
Regulation Number:	21 CFR 886.1290
Class:	Class I
Product Code:	SBN
Premarket Review:	Ophthalmic Devices (DHT1A)
Review Panel:	Ophthalmic

PREDICATE DEVICE IDENTIFICATION
VERVE is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K051684	EYEPORT Vision Training System/ Exercise Your Eyes Inc.	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION

Virtual Eye Rotation Vision Exercises (VERVE) is a software as a medical device (SaMD) intended to provide vision therapy using virtual reality. The device is indicated for prescription use in patients 11 years or older who have convergence insufficiency (CI). VERVE is provided pre-installed on an off-the-shelf tablet and a third-party headset with integrated eye tracking. Data analysis is performed on VERVE's cloud-based server and results are displayed on the tablet.

VERVE uses virtual reality to incorporate effective elements from office-based vergence and accommodative therapy (OBVAT) to treat CI. Traditional OBVAT includes modifying the amount of eye rotation required to complete each exercise, also known as disparity vergence demand. VERVE can modify the vergence demand within a session while the user engages with the software device.

INDICATIONS FOR USE

VERVE is indicated for the treatment for convergence insufficiency in patients aged 11-35 under the supervision of a medical professional by providing therapeutic visual procedures in a virtual reality setting.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

OculoMotor Technologies (OMT) believes VERVE is substantially equivalent to the predicate device based on the information summarized here:

The subject and predicate devices have the same intended use and employ the same fundamental treatment methodology. Both are fixation devices intended to treat convergence insufficiency. The main differences between the subject and predicate devices are the intended use population and their physical designs. The subject device is indicated specifically for patients 11 years of age and older whereas the predicate does not specify pediatric use. Additionally, the subject device relies on a virtual reality headset and tablet to administer treatment while the predicate device uses alternating red and blue lights on a long plastic rod. The subject device uses the headset to perform eye tracking during treatment to measure treatment outcomes whereas the predicate device does not have that feature.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for VERVE. The following tests were performed to demonstrate safety based on current industry standards:

Software Verification

The software development and testing were executed with consideration to IEC 62304 *Medical device software — Software life cycle processes*.

SUMMARY OF CLINICAL TESTING

OMT conducted a clinical study to evaluate VERVE's performance in the treatment of convergence insufficiency. Patients diagnosed with convergence insufficiency were enrolled into the VERVE clinical trial. All 25 patients (ages 10 to 33) completed the study and no dropouts occurred. Treatment (using VERVE software version 3.0.1 on the PICO Neo3 Pro Eye headset) was administered twice a week for 6 weeks, and each treatment session lasted 1 hour. Near point of convergence, amplitude of accommodation, positive fusional vergence, negative fusional vergence, and the convergence insufficiency symptom score (CISS) were recorded before and after treatment.

Results demonstrated VERVE significantly improved near point of convergence (baseline was 10.8±3.8 cm, outcome was 4.9±1.7 cm, change was 5.9±4.0 cm; normal is considered 6 cm or less measured from the bridge of the nose along the midline) and positive fusional vergence (baseline was 11.4±5.7 Δ, outcome was 19.2±6.6 Δ, change was 7.8±10.5 Δ; normal is considered 15 Δ or more) and improvements were clinically relevant. VERVE also significantly improved visual symptoms assessed through the CISS (baseline was 37.2±7.8 points, outcome was 18.7±6.8 points; a score of 21 points or greater is considered clinically symptomatic for young adults (16 points for pediatric) and the higher the score the more symptomatic the patient).

Treatment success in the study was defined as reaching normal ranges for near point of convergence and positive fusional vergence. Overall, 72% (18 out of 25 patients) were categorized as having achieved success, 28% (7 out of 25 patients) were categorized as having improved, and 0% (0 out of 25 patients) were categorized as non-responders.

CONCLUSION

Based on the testing performed, including bench testing, a clinical evaluation and software verification and validation, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use and performance characteristics for the proposed VERVE are assessed to be substantially equivalent to the predicate device.