July 30, 2026

VertigoDx, Inc.
℅ Jerry Sudduth
QA/RA Consultant
Imangel Consulting, Inc.
Contact Address

Re: K260566
Trade/Device Name: SMARTVERTIGO Vestibular Assessment System
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: June 30, 2026
Received: June 30, 2026

Dear Jerry Sudduth:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JOYCE C. LIN -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K260566

Device Name

SMARTVERTIGO™ Vestibular Assessment System

Indications for Use *(Describe)*

The SmartVertigo™ Vestibular Assessment System is indicated for use in the medical office, hospital, and healthcare settings for viewing and recording eye movements in patients with symptoms of dizziness caused by peripheral vestibular disorders who are under the supervision of a clinician. The device records abnormal eye movements with an iPhone camera in response to standard positional maneuvers. The device records, tracks, stores, and displays normal and abnormal eye movements, including vertical, horizontal, and torsional. This device provides no diagnosis and does not provide diagnostic recommendations.

The target population is individuals 12 years of age and older.

Type of Use *(Select one or both, as applicable)*

[X] 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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VertigoDx Inc

510(k) Summary

Device: SMARTVERTIGO™ Vestibular Assessment System

1. Contact Details

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Phone	954 729 1411
Contact	Jerry Sudduth
E-mail	jsudduth999@gmail.com

2. Device

Device Name	SMARTVERTIGO™ Vestibular Assessment System
Common Name	Nystagmograph
Medical Specialty	Neurology
Regulation	882.1460
Classification	Class II
Product Code	GWN

3. Device Description

The SMARTVERTIGO™ Vestibular Assessment System is an iPhone-based diagnostic aid intended for use in medical offices, hospitals, and other healthcare settings for the evaluation of patients aged 12 years and older with dizziness associated with peripheral vestibular disorders. The system consists of an Apple iPhone 14 Pro Max running iOS 16, mounted within a padded, adjustable headset that fully occludes external light to prevent visual fixation. The device records eye movements, including horizontal, vertical, and torsional nystagmus, during clinician-performed positional maneuvers. The scientific basis of the device is founded on established vestibular physiology, specifically the observation that abnormal vestibulo-ocular reflex responses produce characteristic nystagmus patterns that assist in localizing peripheral vestibular pathology. By eliminating visual fixation and enabling high-resolution video capture of the patient's eye, the system facilitates visualization, recording, tracking, storage, and display of eye movements for physician interpretation. All diagnostic and treatment decisions remain the responsibility of the attending clinician.

The device design integrates a rigid polycarbonate/acrylonitrile-butadiene-styrene (PC/ABS) and silicone enclosure with a polyurethane-padded face cushion and adjustable nylon and nylon/polyester hook-and-loop head straps to ensure secure positioning and patient comfort. A rare earth (neodymium) magnet secures interchangeable front plates that support landscape and portrait configurations while maintaining camera alignment with the patient's eye. The enclosed configuration blocks ambient light and stabilizes the iPhone to support consistent image acquisition. Illumination, when required, is provided by the iPhone's integrated LED at its lowest intensity setting. Proprietary software aligns and crops the recorded image to center the pupil and guides the clinician through a structured workflow for standardized testing,

documentation, and secure data management. No external cables or powered accessories are required, and the system relies solely on the iPhone's integrated hardware and software components to achieve its intended performance characteristics.

4. Legally Marketed Predicate and Reference Devices

Predicate: DizzyDoctor® System 1.0.0 (K182214)

Reference: Insight Infrared Video Goggles (K203082)

5. Intended Use/Indications for Use

The SmartVertigo™ Vestibular Assessment System is indicated for use in the medical office, hospital, and healthcare settings for viewing and recording eye movements in patients with symptoms of dizziness caused by peripheral vestibular disorders who are under the supervision of a clinician. The device records abnormal eye movements with an iPhone camera in response to standard positional maneuvers. The device records, tracks, stores, and displays normal and abnormal eye movements, including vertical, horizontal, and torsional. This device provides no diagnosis and does not provide diagnostic recommendations.

The target population is individuals 12 years of age and older.

6. Indications and Technological Comparison

Characteristic	Subject Device	Predicate Device	Reference Device
Regulation / Product Code	882.1460 / GWN	882.1460 / GWN	882.1460 / GWN
Device Class	Class II	Class II	Class II
Indications for Use / Intended Use	The SmartVertigo™ Vestibular Assessment System is indicated for use in the medical office, hospital, and healthcare settings for viewing and recording eye movements in patients with symptoms of dizziness caused by peripheral vestibular disorders who are under the supervision of a clinician. The device records abnormal eye movements with an iPhone camera in response to standard positional maneuvers. The device records, tracks, stores, and displays normal and abnormal eye movements, including vertical, horizontal, and torsional. This device provides no diagnosis and	The DizzyDoctor® System 1.0.0 Eye Movement Monitor is indicated for use in the medical office, and in the home setting for monitoring patients with a diagnosis of dizziness caused by peripheral vestibular disorders who are under the supervision of a physician. The device detects abnormal eye movements in response to standard positional maneuvers by recording, tracking, storing and displaying vertical, horizontal and torsional eye movements. This device provides no diagnosis and does not provide diagnostic recommendations.	The Insight Infrared Video Goggles are intended for viewing and recording eye movements in support of identifying vestibular disorders in patients. The device is intended for use only by a trained healthcare professional in an appropriate healthcare setting. This device provides no diagnoses nor does it provide diagnostic recommendations. The target population is 12+ years of age.

Characteristic	Subject Device	Predicate Device	Reference Device
	does not provide diagnostic recommendations. The target population is individuals 12 years of age and older.		
Intended Operator / User	Trained healthcare professionals	Physician	Trained personnel only, such as audiologists, ENT doctors, physicians, vestibular rehabilitation specialists, or licensed healthcare personnel with a similar level of qualifications.
Clinical Setting	Medical office, hospital, and healthcare settings	Medical office and in the home setting	Appropriate healthcare setting
Target Population	12+ years of age	Not disclosed	12+ years of age
Anatomical Site	Human eyes (eye movements / nystagmus)	Human eyes (eye movements / nystagmus)	Human eyes (eye movements / nystagmus)
Principle of Operation	iPhone mounted in light-occluding goggles; iPhone camera records eye movements during guided positional maneuvers; videos stored and viewed via VertigoDx app.	iPhone mounted in light-occluding goggles; iPhone camera records eye movements during guided positional maneuvers; videos uploaded for physician review.	N/A
Camera / Optics	Physician's iPhone, which is affixed at eye level to the goggle's Mounting Plate that aligns the iPhone camera to the patient's eye.	Patient's or physician's iPhone, which is affixed at eye level to the goggle's Mounting Plate that aligns the iPhone camera to the patient's eye.	N/A
Illumination Source	iPhone's integrated LED	LED side lights built into goggle	N/A
Light Occlusion / Fixation Control	Light occluding goggle frame with padded face cushion to block external light	Light occluding goggle frame with built-in light shielding to block external light	N/A
Number of Eyes Recorded	1	1	N/A
Eye Movements Captured	Vertical, horizontal, and torsional	Vertical, horizontal, and torsional	N/A
Data Output	Real-time viewing on iPhone and stored video of eye movements	Stored video of eye movements	Real-time viewing on computer monitor and stored video of eye movements
Connectivity / Host System	iPhone is a closed system that records and stores videos and data; uploads recordings to secure web portal or cloud for remote	iPhone uploads recordings to web portal for physician viewing on desktop/laptop	N/A

Characteristic	Subject Device	Predicate Device	Reference Device
	viewing by clinician on laptop/desktop		
Power Source	iPhone battery (goggle is not powered)	iPhone battery plus CR2 battery for goggle LEDs	N/A
Patient-Contact Materials	Durable plastic shell with face cushion (PC+ABS, silicone)	Durable plastic shell with face cushion	N/A

7. Non-Clinical Test Summary

To establish substantial equivalence, non-clinical testing was conducted.

7.1. Software

The VertigoDx App is a mobile Software as a Medical Device (SaMD), compliant to IEC 62304, is intended to assist healthcare professionals in documenting, organizing, and supporting the clinical assessment of vertigo and balance disorders. The software performs structured data capture, symptom documentation, guided test documentation, and report generation for clinician review. Similar to the identified predicate device, the VertigoDx App provides decision-support functionality based on clinician-entered data and does not independently diagnose, treat, or control therapy. The clinician remains responsible for clinical interpretation and final medical decision-making.

7.2. Illumination

The SmartVertigo Vestibular Assessment System utilizes the display illumination of a commercially available smartphone (iPhone 14 Pro Max) as a low-intensity, diffuse white-light source to illuminate the peri-ocular region during video capture of eye movements. The system operates at a fixed distance of 9 cm from the subject's eyes, producing an illuminance of 17–40 lux and luminance of 5–13 cd/m², with no UV or IR emissions. Testing was conducted using a Digital Lux Meter (model LX1330B) under controlled conditions to measure light output and assess compliance with applicable photobiological safety standards, including ANSI Z80.36-2021 and IEC 62471:2006.

Based on luminance measurements and comparison with these standards, the SmartVertigo Vestibular Assessment System qualifies as an Exempt light source (RG0) with no risk of blue-light retinal, thermal retinal, UV, or IR hazards. Exposure duration is limited to 2-minute intervals per test, with a maximum cumulative exposure of 14 minutes, ensuring retinal exposure remains far below defined hazard thresholds. The device incorporates safety features such as a software lock to maintain minimum brightness, a fixed working distance of 9 cm via the smartphone mount, and user instructions to prevent manual brightness increases.

7.3. Human Factors/Usability

A summative usability validation study for the SmartVertigo was conducted in compliance with IEC 62366-1:2015+A1:2021 and FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices," to support safe and effective use by its intended user population (clinicians, technicians, healthcare personnel). Fifteen participants, aged 22–58 years, completed critical tasks using the finalized Instructions for Use (IFU) without coaching. All participants achieved ≥76% task success, with a mean score of 43.7/50, and no non-recoverable or critical errors were observed. Minor recoverable errors, such as headset adjustment and software navigation, were resolved using the IFU, which was rated 100% clear, easy to read, and helpful.

The study demonstrated that the device and IFU adequately mitigate use-related risks and support the system's safety and effectiveness compared to the predicate.

8. Conclusion

The subject and predicate devices have the same intended use, similar technological characteristics, and the same fundamental scientific principles of operation. The minor differences in illumination source, data handling configuration, and clinical setting are addressed by the non-clinical and HF testing described above and do not introduce different questions of safety or effectiveness.

Therefore, we can conclude these devices are substantially equivalent.