November 12, 2020

Vestibular First
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K203082
Trade/Device Name: Insight Infrared Video Goggles
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: October 10, 2020
Received: October 13, 2020

Dear Dave Yungvirt:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Malvina Eydelman, M.D.
Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Insight Infrared Video Goggles

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K203082 510(k) Summary

Date Prepared: 11/4/2020

Submitter Information

Vestibular First
9 Mather Ave
Broomall, PA 19008
United States
VestibularFirst.com

Contact Information

Connie Qiu
Regulatory Consultant
M-Squared Associates
(347) 954-0411
cqiu@msquaredassociates.com

Device Identification

Proprietary Name - Insight Infrared Video Goggles

Common Name - Infrared Video Goggles, Video Frenzels, Video Goggles

Classification Name - Nystagmograph (21 CFR § 882.1460)

Product Code: GWN

Device Class: Class 2

Panel: Neurology

Predicate Devices

Primary Predicate Device: Micromedical VisualEyes 515/ 525, ***K152112***

Secondary Predicate Device: Interacoustics 2D-VOGfw System (VN415b) , **K072254**

Indications for Use

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.

Device Description

The Insight Infrared Video Goggles system displays and records eye movements on a computer from cameras mounted to goggles worn by a patient The eye movements called nystagmus are part of the body's balance system and can be analyzed by a trained clinician to provide objective information during a vestibular exam. The goggles are designed to block all external light from the patient's eyes so they are unable to fixate on anything in their visual field. This is an important performance characteristic of the googles since the eyes can suppress abnormal nystagmus when not occluded. The goggles have a durable plastic shell that houses two (2) cameras, infrared LED lights, two (2) switch-driven visible lights, and a face cushion. The goggles connect to the computer with a 4 m USB cable and are designed to be worn by the patient for 10 to 15 minutes on average in various body positions as directed by the clinician.

Predicate Device Comparison

We have chosen to compare the Insight Infrared Video Goggles with the primary predicate device, VisualEyes 515/525 software (K152112) and the secondary predicate device, 2D-VOGfw/VN415b system for the following reasons:

- The predicate systems have the same classification (Class II) and product code (GWN)
- The predicate systems, when used together as intended, use software on a computer to display and record eye movements recorded from cameras mounted

to a video goggle in the same manner as the Insight Infrared Video Goggles

- The predicate systems have the same or similar indications for use, intended operator, and principle of operation, as described in detail in ***Table 1***
- Multiple predicate devices are necessary and appropriate to support substantial equivalence because the manufacturer Interacoustics A/S have separate hardware and software submissions to support multiple system configurations. Additionally, our primary predicate device specifically references our secondary predicate device as being the compatible hardware system for the software. The Insight Infrared Video Goggles combine both hardware and software components and each will be compared to their respective predicate device as applicable.

Table 1 - Substantial Equivalence Comparison

	Insight Infrared Video Goggles	**Primary Predicate Device: VisualEyes 515/525 (K152112)**	**Secondary Predicate Device: 2D-VOGfw System/VN415b (K072254)**	**Equivalence**
Classification	Class II	Class II	Class II	Same
Product Code	GWN	GWN	GWN	Same
Device Description	The Insight Infrared Video Goggles system displays and records eye movements recorded from cameras mounted to a video goggle. The videos can be used by a trained medical professional to assist in diagnosing vestibular disorders.	VisualEyes 515/525 is a software program that displays, records, and analyzes eye movements recorded from a camera mounted to a video goggle. This system can utilize the 2D-VOGfw/VN415b system which is the subject of the hardware comparison. The videos can be used by a trained medical professional to assist in diagnosing vestibular disorders.	This system consists of a PC or laptop, a 2D-VOGfw Goggle, and a software platform that by licensing enables different levels of functionality recognized as the VN415m, VN415b, VO425m, VO425b products. The "m" indicates monocular, and the "b" indicates binocular, indicating the number of cameras utilized by the related system. The 2D-VOGfw Goggles component comprises housing and one or two cameras depending on the license obtained for this system. The 2D-VOGfw Goggle is connected to the computer via a standard Firewire connection.	Similar. The 515/525 software has the additional feature of eye tracking and related data analysis. The 2D-VOGfw/VN415b system can be used for an additional assessment known as caloric testing. These differences do not raise new questions of safety or effectiveness.

Indications for use	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.	The VisualEyes 515/525 system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by the use of a goggle mounted with cameras. These images are measured, recorded, displayed, and stored in the software. This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders. The target population for VisualEyes 515/525 system is 5 years of age and up.	VN415m, VN415b, VO425m, VO425b systems provide information to assist in the Oculographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by use of goggle mounted cameras. These images are measured, recorded, displayed and stored in the associated software. This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders.	Similar. Same intended use, intended user, and intended use environment, but different age population. This difference do not raise new questions of safety or effectiveness.
Intended Operator	Insight Infrared Video Goggles are to be used by trained personnel only, such as audiologists, ENT doctors, physicians, vestibular rehabilitation specialists, or licensed healthcare personnel with a similar level of qualifications. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.	The VisualEyes VNG system is to be used by trained personnel only, such as audiologists, ENT surgeons, doctor's, hearing healthcare professionals or personnel with a similar level of qualifications. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.	Trained medical professional	Same
Principle of Operation	Infrared video cameras mounted inside goggles display the patient's eye movements on a connected computer. The goggles are light-proof, however a visible light can be turned on inside the goggles by the clinician from an external switch. The cameras are connected to the computer via USB cable. The clinician views and optionally records the eye movements using software on the connected computer.	Software connects to the cameras which allows it to display, record, and produce graphs of the patient's eye movements. Eye tracking provides quantitative data to the clinician which can be used in conjunction with the video to diagnose and treat vestibular dysfunctions.	Infrared video cameras mounted inside goggles display the patient's eye movements on a connected computer. The goggles are light-proof, however a visible light can be turned on inside the goggles by the clinician from an external switch. The cameras are connected to the computer via a standard Firewire cable. The clinician views and optionally records the eye movements using software on the connected computer.	Similar. The Visual Eyes 515/525 has additional capabilities via eye tracking software. The 2D-VOGfw/VN415b system utilizes a Firewire instead of USB cable. These differences do not raise new questions of safety or effectiveness.
Materials	PC+ABS, Silicone	N/A	Exact materials unknown	Similar. Both housings are made of durable plastic and have a foam or silicone component contacting the face, although

				the exact materials are not specified by the 2D-VOGfw/VN415b system. These differences do not raise new questions of safety or effectiveness.
Infrared (IR) Source	(2) IR LEDs @ 940 nm wavelength	N/A	(2) IR LEDs @ 950 nm wavelength	Similar. There is a 10 nm difference in wavelength, but these differences do not raise new questions of safety or effectiveness.
Infrared (IR) Control	On when goggles are plugged in and system is on.	N/A	On when goggles are plugged in and system is on.	Same
Light for visual focus point	Yes	N/A	Yes	Same
Light blocking opaque goggles	Yes	N/A	Yes	Same
Energy Source	External via USB powered by computer	Software powered by connected computer	External via Firewire powered by computer	Similar. 2D-VOGfw/VN415b system is powered via Firewire by computer, and the VisualEyes 515/525 software is powered by the computer as well. Insight goggles are powered via USB by computer. These differences do not raise new questions of safety or effectiveness.
Components	-Binocular video goggles -Face cushion -USB 2.0, 4 m length -Travel Case -Off-the-shelf software with viewing and recording features	-Proprietary software with eye tracking as well as viewing and recording features	-Binocular video goggles -Firewire cable, 4.5 m length	Similar. Off-the-shelf software is used with the Insight Infrared Video Goggles, while the VisualEyes 515/525 utilizes its own proprietary software with eye tracking. The cable for the 2D-VOGfw/VN415b system has a cable that is 0.5 m longer than the cable for the Insight goggles. The Insight goggles come with a travel case for use to store and transport the goggles. These differences do not raise new questions of safety or effectiveness.

Weight	530 g (face cushion, goggles, and cable)	N/A	345 g (occluded view) without cables	Similar. The Insight goggles weigh more than the 2D-VOGfw/VN415b system's goggles, however these differences do not raise new questions of safety or effectiveness.
Interface to Control Device	(1) Visual fixation light is controlled via a switch located on top of goggle body (2) Camera view is controlled by operator interacting with off-the-shelf software	Computer with a standard keyboard and mouse	Two options to control both the visual fixation light and camera view: (1) Via software directly (2) Via remote control that can directs the software	Similar. 1. The visual fixation light is controlled by a physical switch in the Insight Infrared Video Goggles while it is controlled by a remote or by the software in the VisualEyes 515/525 plus 2D-VOGfw/VN415b system; 2. The camera view is controlled by software in the Insight Infrared Video Goggles while it is controlled by a remote or by the software in the VisualEyes 515/525 plus 2D-VOGfw/VN415b system. These differences do not raise new questions of safety or effectiveness.
Video Recording and Playback Capability	Yes (off-the-shelf software)	Yes	Yes (used in conjunction with the 515/525 software)	Same
System Interface	A computer interface that allows for display of both eyes on computer monitor and provides power for the video cameras and the LEDs	A software interface that allows for display of video and charts of eye movements	A computer interface that allows for display of both eyes on computer monitor and provides power for the video cameras and the LEDs	Similar. The Visual Eyes 515/525 can provide charts of eye movements via eye tracking software. These differences do not raise new questions of safety or effectiveness.

Summary of Non-Clinical Performance Data

Table 2 - Electrical and Safety Test Results

Test	Title	Results
ANSI AAMI ES 60601-1:2005 (R) 2012+AMD1:2012	Medical Electrical Equipment. Part 1: General requirements for safety	Pass
IEC 60601-1-2:2014	Medical Electrical Equipment. Part 2: Electrical Safety	Pass
IEC 62471-1:2006	Photobiological safety of lamps and lamp systems	Pass

Table 3 - Biocompatibility Test Results

Test	Title	Method	Results
ISO 10993-5:2009	Biological evaluation of medical devices - part 5: tests for in vitro **Cytotoxicity**	V-79 cell lineage Extract: DMEM culture medium + 10% Fetal bovine serum and 1% penicillin/Streptomycin kept in a Schott flask at 37C for 24 hours	Non-cytotoxic
ISO 10993-10:2010	Biological evaluation of medical devices - part 10: tests for **Skin Sensitization**	Guinea Pig Maximization Test (GPMT)	Non-sensitizing
ISO 10993-10:2010	Biological evaluation of medical devices - part 10: tests for **Irritation**	Animal Irritation Test - White Rabbit	Non-irritating

Performance Testing

ANSI/ASA S3.45-2009(R)2014 American National Standard Procedures for Testing Basic Vestibular Function is a voluntary standard specific to the GWN product code associated with infrared video goggles for vestibular assessment.

Given the Insight Infrared Video Goggles's function, it was appropriate to perform a performance test which requires a trained clinician to view the eye movements during the relevant Vestibular Function Tests of spontaneous nystagmus, gaze-evoked nystagmus, and positioning and positional nystagmus testing, without the use of eye tracking software. Therefore, the VisualEyes Video Eye Monitor (K964325, Product Code: GWN) was selected as the comparative reference device to the Insight Infrared Video Goggles for this performance test, since unlike the 2D-VOGfw/VN415b system plus VisualEyes 515/525 software, both of the compared devices display eye movements during testing but do not provide caloric testing, and neither utilizes eye tracking software. In addition, both the Insight Infrared Video Goggles and the VisualEyes Video Eye Monitor (K964325) have the same classification (Class II) and product code (GWN) and share common intended use and fundamental technology, and therefore they were used in comparative performance testing to support substantial equivalence.

During the Performance Testing, for each of the subjects, two trained clinicians viewed the eye movements of the same 5 subjects during the relevant Vestibular Function Tests: (1) spontaneous nystagmus, (2) gaze-evoked nystagmus, and (3) positional and positional nystagmus testing. One round of testing was performed with the subject wearing the Insight Infrared Video Goggles (repeated with that device for 2 rounds total to confirm reliability), and the other round of testing was performed with the VisualEyes Video Eye Monitor (K964325) goggles. The Insight Infrared Video Goggles were rated "YES" for all criteria for all subjects tested (Yes/Pass for all 5 subjects for each of the 2 clinicians), including ability to view the eye movements and eye movements displayed clearly enough for assessment. This resulted in 100% PASS (performance present), meeting the acceptance criteria fully. Therefore, the results of this study demonstrate equivalent performance between the Insight Infrared Video Goggles and the VisualEyes Video Eye Monitor (K964325) goggles for the vestibular tests that they share in common.

Discussion of Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence.

Conclusion

The Insight Infrared Video Goggles have a smaller set of testing and software features, all of which are similarly present in the 2D-VOGfw/VN415b system plus VisualEyes 515/525 software. The basis of the substantial equivalence determination is limited to the common intended use and technological characteristics that the two systems share. The two devices share the same intended use, the same fundamental technology, and the same operating principle. Any differences between the two devices are minor and do not raise any new questions about safety and effectiveness. Therefore, the Insight Infrared Video Goggles are substantially equivalent to the 2D-VOGfw/VN415b system plus VisualEyes 515/525 software.