August 12, 2020

Interacoustics A/S
Erik Nielson
Director, Regulatory & Compliance
Audiometer Alle 1
Middelfart, 5500
Denmark

Re: K200534
Trade/Device Name: VisualEyes
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: July 10, 2020
Received: July 13, 2020

Dear Erik Nielson:

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.
Office Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200534

Device Name
VisualEyes 515 / VisualEyes 525 / VisualEyes 505

Indications for Use *(Describe)*
The VisualEyes system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by 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 system is 5 years of age and above

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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510(K) SUMMARY

VisualEyes 505/515/ 525

Submitter Information:

Company Name	Interacoustics A/S
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Contact Person	Erik Nielsen, Director, Regulatory & Compliance
Date Summary Prepared	August 07, 2020

Device Identification:

Trade Name	VisualEyes 505 VisualEyes 515 VisualEyes 525
Common Name	Vestibular analysis device
Classification Name	Nystagmograph, apparatus, vestibular analysis
Product Code Class	GWN
Panel	Neurology
Device Class	Class II (According to 21 CFR 882.1460)

Predicate Device:

Predicate Device	VisualEyes 505/515/ 525
Manufacturer	Interacoustics A/S
510(k) No.	K163149
Date Cleared	04/26/2017

Reference devices:

Reference Device	VIDEO EYE TRAKKER (Aka Spectrum)
Manufacturer	MicroMedical Technologies Inc
510(k) No.	K964646
Date Cleared	07/15/1997

Reference Device	EyeSeeCam VHIT
Manufacturer	Interacoustics A/S
510(k) No.	K131681
Date Cleared	09/06/2013

Device Description

VisualEyes 505/515/ 525 is a software program that analyzes eye movements recorded from a camera mounted to a video goggle. A standard Video Nystagmography (VNG) protocol is used for the testing. VisualEyes 505/515/ 525 is and update/change, replacing the existing VisualEyes 515/525 release 1 (510(k) cleared under K152112).

The software is intended to run on a Microsoft Windows PC platform. The "525" system is a full featured system (all vestibular tests as listed below) while the "515" system has a subset of the "525" features. "505" is a simple video recording mode.

The VisualEyes 505/ 515/ 525 software is designed to perform the following vestibular tests:

Test	Availability
Calibration	515 / 525
Spontaneous nystagmus	515 / 525
Dix-Hallpike	515 / 525
Positional	515 / 525
Caloric	515 / 525
Gaze	525
Smooth Pursuit	525
Random Saccade	525
Saccadometry	525
Optokinetic	525
Sinusoidal Harmonic Acceleration	515/525
Step Velocity	515/525
VOR Suppression	515/525
Visual VOR	515/525
Subjective Visual Vertical (SVV)- Static	525
Subjective Visual Vertical (SVV)- Dynamic	525
Video Frenzel	525
Ocular Counter Roll	525
VORTEQ AHR	525
vHIT for VORTEQ	525
Dynamic Visual Acuity (DVA)	515/ 525/505
Dix-Hallpike Advanced	
Lateral Head Roll	
vHIT for EyeSeeCam - Lateral - LARP - RALP - SHIMP	515/525/505
Video recording	505

Indications for Use	The VisualEyes system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by 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 system is 5 years of age and above.
Intended operator	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.
Technological characteristics	The VisualEyes is a software system is intended to incorporate various goggle/cameras, rotary chairs, irrigators and other accessories

Comparison of technological characteristics with predicate device

We have chosen to compare the VisualEyes 3 software with the VisualEyes 2 as the characteristics of VisualEyes 3 is most similar to VisualEyes 2. The technological principles for VisualEyes 3 is based on refinements from VisualEyes 2 and adoptions of functionality of the two reference devices.

Comparison tables

VisualEyes 3 to Predicate Device VisualEyes 2

Functionality Description	Equivalence
Indications for use: The VisualEyes system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by 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 system is 5 years of age and above	Same
Spontaneous Nystagmus Test	Same
Gaze Test	Same
Smooth Pursuit Test	Same
Saccade Test	Same
Optokinetic Test	Same
Dix-Hallpike Test	Same
Positional Test	Same
Caloric Test	Same

SHA Test	Same
Step Test	Same
VOR Suppression Test	Same
Saccadometry	This is the same. Saccadometry is a broad term that means saccadic eye movements being measured. The VisualEyes saccade test involves a single stimulus (dot) moving from one position to the other. The patient either looks to or away from the dot. There is no difference in the stimulus presentation between the predicate and new software. The only difference is that for the antisaccade the patient looks away from the target instead of towards the target. The exact same measures of latency, accuracy and velocity are recorded and plotted. Since the stimulus presented and the algorithms have not changed for the saccade tests there are no device safety or effectiveness differences between the two devices.
Advanced Dix Hallpike Test	This is the same. For the Advanced Dix Hallpike there are no changes in how the test is performed. The only change was the inclusion of the new torsional eye tracker from Johns Hopkins. This has been verified and demonstrates that there are no device safety or effectiveness differences between the two devices.

VisualEyes 3 software also adopts functions from the Micromedical Technologies Spectrum software as the Spectrum supports many of the protocols that are being ported into VisualEyes 3.
The VHIT function is adopted into VisualEyes 3 software from EyeSeeCam VHIT

Functionality adopted from reference device VIDEO EYE TRAKKER

Functionality Description	**Equivalence**
ENG	Same
Ocular Counter roll	Uses the Johns Hopkins torsional algorithm not the Spectrum tracking algorithm
VORTEQ Active Head Rotation (AHR)	Same
VORTEQ Dynamic Visual Acuity (DVA)	Same
VORTEQ Video Head Impulse Test (vHIT)	Same
Dynamic Subjective Visual Vertical (SVV) in Orion AT chair	Same
Static Subjective Visual Vertical in the Orion Comprehensive Chair	Same
Torsional Tracking Algorithm	This is the same. Improved in release VisualEyes 3 with the addition of libraries from Johns Hopkins. This has been verified and demonstrates that there are no device safety or effectiveness differences between the two devices.

Functionality adopted from reference device EyeSeeCam

Functionality Description	Equivalence
vHIT	Same

Verification and validation summary

In order to validate the new software, bench testing was conducted internally, and beta testing was conducted with various groups in different geographical locations externally. The purpose of the testing is to confirm that the results collected on the updated VisualEyes software generated the same clinical findings as the existing predicate devices.

The beta testing was conducted in external sites that had either MMT or IA existing predicate devices. All data was exported from the external beta sites and transferred to licensed internal clinical audiologists who compared the test results for substantial equivalency. The data was collected sequentially, which involved having the same subject tested on VisualEyes and then tested again on either IA or MMT predicate devices. The data sets were compared to determine if there were any statistically significant differences in the data collected from predicate and current devices.

Summary

There were no differences found in internal bench testing comparisons or the external beta testing statistical comparisons. VisualEyes 505/515/525 performs substantially equivalent to the predicate devices used for the validation.
For the statistical comparison, all data sets showed a negligible statistical difference beneath the specified acceptance criteria.

It is the professional opinion of both clinical reviewers of the validation that all the data between the new VisualEyes software and the data collected and analyzed with both predicate devices are substantially equivalent. There are no differences between any of the products tested.

Conclusion

We have compared key issues for the VisualEyes 505/515/ 525 and the predicate devices. We have performed a comparison validation between VisualEyes 505/515/ 525 and the predicate devices.

Any deviations between VisualEyes 505/515/ 525 and predicate devices are appraised to have no adverse effect on the safety and effectiveness of the device.

We trust that the results of these comparisons demonstrate that the VisualEyes 505/515/ 525 is substantially equivalent to the marketed predicate devices (K163149).