DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 26, 2017

Interacoustics A/S
Mr. Erik Nielsen
Director, Regulatory & Compliance
Audiometer Allé 1
Middelfart 5500
Denmark

Re: K163149
Trade/Device Name: VisualEyes
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: March 24, 2017
Received: March 29, 2017

Dear Mr. Nielsen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163149

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+

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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Section 05 - 510(k) Summary

510(K) SUMMARY

VisualEyes 505/515/ 525

Submitter Information:

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Contact Person	Erik Nielsen, Director, Regulatory & Compliance,
Date Summary Prepared	November 1, 2016

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 1:

Predicate Device	VisualEyes 515/ 525
Manufacturer	Interacoustics A/S
510(k) No.	K152112
Date Cleared	12/29/2015

Predicate Device 2:

Predicate Device	VIDEO EYE TRAKKER
Manufacturer	Micromedical Technologies Inc.
510(k) No.	K964646
Date Cleared	07/15/1997

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:

- Spontaneous Nystagmus Test (Included in: VisualEyes 525 and 515)
- Gaze Test (Included in: VisualEyes 525)
- Smooth Pursuit Test (Included in: VisualEyes 525)
- Saccade Test (Included in: VisualEyes 525)
- Optokinetic Test (Included in: VisualEyes 525)
- Dix-Hallpike (Included in: VisualEyes 525 and 515)
- Positional Test (Included in: VisualEyes 525 and 515)
- Caloric Test (Included in: VisualEyes 525 and 515)
- SHA (Included in: VisualEyes 525 and 515)
- Step (Included in: VisualEyes 525 and 515)
- Visual VOR (Included in: VisualEyes 525 and 515)
- VOR Suppression (Included in: VisualEyes 525 and 515)
- Visual Eyes 505 (included in VisualEyes 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+

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 system consists of a head mounted goggle/mask, a camera unit and a software application running on a standard PC.

We have chosen to compare the VisualEyes 505/ 515/ 525 software with current VisualEyes 515/525 **and** VIDEO EYE TRAKKER (a.k.a. SPECTRUM) for the following reasons.

- VisualEyes 505/ 515/ 525 (VisualEyes revision 2) is an update/change of the VisualEyes 515/ 525 (VisualEyes revision 1)
- Video Eye Trakker includes the updated functionality in VisualEyes revision 2 and has been used for rotational chair tests.
- The predicate systems have the same medical purpose so it is easy to compare validation results.
- Both predicate systems have previously obtained FDA 510(k) clearance

Comparison table
VisualEyes 505/515/ 525 (revision 2)
Versus
VisualEyes 515/ 525 (revision 1)

NOTE: In the comparisons table the tests present full system ("525" system).

Description	VisualEyes 515/ 525 (rev 1)	VisualEyes 505/515/ 525 (rev 2)	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+	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+	Same
Test options	Spontaneous Nystagmus Test	Spontaneous Nystagmus Test*	Same. This test is as described in ANSI S3.45 section 5
	Gaze Test	Gaze Test	Same This test is as described in ANSI S3.45 section 5
	Smooth Pursuit	Smooth Pursuit	Same This test is as described in ANSI S3.45 section 7

Description	VisualEyes 515/ 525 (rev 1)	VisualEyes 505/515/ 525 (rev 2)	Equivalence
	Saccade Test	Saccade Test	Same This test is as described in ANSI S3.45 section 6
	Optokinetic Test	Optokinetic Test	Same This test is as described in ANSI S3.45 section 8
	Dix-Hallpike	Dix-Hallpike*	Same This test is as described in ANSI S3.45 section 8
	Positional Test	Positional Test*	Same This test is as described in ANSI S3.45 section 8
	Caloric Test	Caloric Test*	Same This test is as described in ANSI S3.45 section 9
	Video recording mode	Video recording mode (VE505)	Same.
	Reporting tools	Reporting tools	Same
Algorithms	IA Curver tracker	IA Curve tracker	Same – An algorithm comparison evaluation has been performed. This evaluation shows high correlation between the algorithm used in the predicate device and the new as the algorithms are the same
Hardware Platform	2D-VOG GOGGLES, 2D-VOG SYSTEM	2D-VOG GOGGLES, 2D-VOG SYSTEM	Same

All tests are included in the VisualEyes 525. Tests marked with * is the only tests present in the VisualEyes 515

Comparison table
VIDEO EYE TRAKKER (K964646)
Versus
VisualEyes 515/ 525

Note. The VIDEO EYE TRAKKER (K964646) is currently marketed under the name SPECTRUM software for the Micromedical VisualEyes

Description	VIDEO EYE TRAKKER	VisualEyes 515/ 525	Equivalence
Indications for use	The device is used to non-invasively record horizontal and vertical eye movements of patients during routine electronystagmography (ENG) testing of vestibular function using miniature video cameras and pupil tracking hardware. The device is an alternative to skin electrodes and a physiologic signal amplifier for monitoring eye position.	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+	Similar See discussion of indications for use below.
	SHA (Sinusoidal Harmonic Test)	SHA (Sinusoidal Harmonic Test)	Same See discussion below this table
	Step Test	Step Test	Same See discussion below this table
	Visual VOR	Visual VOR	Same See discussion below this table
	Visual Suppression	Visual Suppression	Same See discussion below this table

Discussion, Similarities in indications for use

Note. This is identical with the discussion in the 510(k) submission for revision 1 of VisualEyes system

VIDEO EYE TRAKKER vs. VisualEyes

VIDEO EYE TRAKKER	VisualEyes	Discussion
Routine electronystagmography	Assists in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders	The term "electronystagmography" is not relevant in this application as video is used but "Routine nystagmography" and "nystagmographic evaluation" have equivalence indications
Using miniature video cameras and pupil tracking hardware	Recorded by use of a goggle mounted with cameras	Camera method is identical
No population age limits	Population limit is age above 5 years	The age limitation (5 years of age +) has been added as the system is not designed for children under 5 as the goggle does not fit very small faces well. We appraise it as similar indications as it is a practical restriction.

Summary of IFU similarities

We appraise that the slightly different phrasing in the indications for use are the only deviation in the comparisons. The deviations are discussed above and appraised to be substantially equivalent and hence do not raise any issues regarding safety and efficiency

Performance Tests

We presented a comparison of the subject device and the predicate devices to demonstrate that the key algorithms for detecting and analysing nystagmus were similar. The demonstration was carried out as a side by side comparison where the same patient was analysed by the subject device and the predicate device simultaneously. All tests were performed on test subjects with conjugate eye movements. This means that an eye movement on one eye will match the movement of the other eye. One camera recorded the left eye and was processed in the predicate device and the other recorded the right eye and was processed in subject device. All results showed equivalence between the predicates and the subject, this means that results processed in predicates are showing equivalence to results from the subject device.

Clinical tests
We have performed clinical comparisons between the three systems. These activities, testing and validation show that VisualEyes 505/515/ 525 perform as specified and is safe and effective.

Discussion of differences
We did not find any essential or major differences between the devices.

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. All similarities and differences have been discussed. We trust that the results of these comparisons demonstrate that the VisualEyes 505/515/ 525 is substantially equivalent to the marketed 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.