



Food and Drug Administration  
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December 29, 2015

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

Re: K152112  
Trade/Device Name: Visualey  
Regulation Number: 21 CFR 882.1460  
Regulation Name: Nystagmograph  
Regulatory Class: Class II  
Product Code: GWN  
Dated: November 28, 2015  
Received: December 2, 2015

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,

**Srinivas Nandkumar -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

## Indications for Use

510(k) Number (if known)

K152112

Device Name

VisualEyes 515 /

VisualEyes 525

Indications for Use (Describe)

The VisualEyes 515/ VisualEyes 525 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 515/525 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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**510(K) SUMMARY**

VisualEyes 515/ 525

**Submitter Information:**

Company Name	Interacoustics A/S
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Contact Person	Erik Nielsen, Director, Regulatory & Compliance,
Date Summary Prepared	July 21 2015

**Device Identification:**

Trade Name	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	VN415M, VN415B, VO425M, V0425B, 2D-VOG GOGGLES, 2D-VOG SYSTEM
Manufacturer	Interacoustics A/S
510(k) No.	K072254
Date Cleared	02/05/2008

**Predicate Device 2:**

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

**Device Description** VisualEyes 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 515/ 525 is replacing the existing Micromedical Technologies Spectrum vestibular testing software system and Interacoustics VN415 and VO425 vestibular testing software (510(k) cleared under K964646 and K072254). The software system will work with the existing Micromedical VisualEyes Goggle and Interacoustics VN415/VO425 Goggle. The goggle hardware is not part of this submission and is still assumed covered by K964646 and K072254. 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 limited number of tests (indicated with a \* below).

VNG in general is used to record nystagmus during oculomotor tests such as saccades, pursuit and gaze testing, optokinetics and also calorics. The VisualEyes 515/ 525 software performs the following standard vestibular tests: \*Spontaneous Nystagmus, Gaze, Smooth Pursuit, Saccade, Optokinetic, \*Positionals, \*Dix-Hallpikes and \*Caloric tests. These are exactly the same standard tests that are performed in the predicate devices and are described in the ANSI standard (**ANSI S3.45-1999**, “American National Standard Procedures for Testing Basic Vestibular Function”). There are no difference in any settings or parameters in these default tests in any of the devices. The clinical validation tests showed that each test was performed in exactly the same manner and resulted in similar findings when comparing VE525 to the predicate devices.

**Indications for Use** The VisualEyes 515/ VisualEyes 525 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 515/525 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.

**Product Comparisons - Indications for use**

We have chosen to compare the VisualEyes 515/ 525 software with VN415M, VN415B, VO425M, VO425B, 2D-VOG GOGGLES, 2D-VOG SYSTEM and VIDEO EYE TRAKKER for the following reasons.

- The product is a joint development between Micromedical Technologies and Interacoustics to create a mutual software platform for the companies' eye tracking systems
- VisualEyes 515/ 525 supports the hardware (goggles) from both systems
- Both predicate systems have previously obtained FDA 510(k) clearance
- Both predicate systems have the same medical purpose so it is easy to compare validation results

**VN415m, VN415b, VO425m, VO425b vs. VisualEyes 515/ 525**

We appraise that the indications for use for these two systems are similar as both systems claim:

<b>VN415m, VN415b, VO425m, VO425b</b>	<b>VisualEyes 515/ 525</b>	<b>Discussion</b>
Assist in the Oculographic evaluation, diagnosis and documentation of vestibular disorders.	Assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders	The word nystagmographic is used instead of Oculographic as it is currently a more general term in literature
Recorded by use of goggle mounted cameras	Recorded by use of a goggle mounted with cameras	Same
This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders.	This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders.	Same intended operator group
No population age limits	Population limit is 5 years of age +.	The age limitation (5 years of age +) has been added as the system is not designed for children under age 5 as the goggle does not fit very small faces well. We appraise it as similar indications as it is a practical restriction.

**VIDEO EYE TRAKKER vs. VisualEyes 515/ 525**

<b>VIDEO EYE TRAKKER</b>	<b>VisualEyes 515/ 525</b>	<b>Discussion</b>
Routine electronystagmography	Assist 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 5 years of age +.	The age limitation (5 years of age +) has been added as the system is not designed for children under age 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. We have reviewed the literature for articles about vestibular testing. All these activities, testing and validation show that VisualEyes 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 515/ 525 and the predicate devices. We have performed a comparison validation between VisualEyes 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 515/ 525 is substantially equivalent to the marketed predicate devices.

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