August 12, 2020

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

Re: K200529
Trade/Device Name: Orion Reclining, Orion Auto Traverse, Orion Comprehensive
Regulatory Class: Unclassified
Product Code: LXV
Dated: July 10, 2020
Received: July 13, 2020

Dear Erik 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. 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)*
K200529

Device Name
Orion Reclining, Orion Auto Traverse, Orion Comprehensive

Indications for Use *(Describe)*
The Orion rotary chair is an optional accessory for VisualEyes 525/ VisualEyes 515 eye movement recording systems.

The VisualEyes™ system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. VNG testing evaluates nystagmus using goggles mounted with cameras. These images are measured, recorded, displayed and stored in the software. This information can then be used by a trained medical professional to assist in diagnosing vestibular disorders. The target population for videonystagmography is five 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

Orion Rotary Chair

Submitter Information:

Company Name	Interacoustics A/S
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e-mail	erni@demant.com
Contact Person	Erik Nielsen, Director, Regulatory & Compliance
Date Summary Prepared	August 11, 2020

Device Identification:

Trade Name	Orion Reclining Orion Auto Traverse Orion Comprehensive
Common Name	Rotary chair
Classification Name	Apparatus, vestibular analysis
Product Code	LXV
Classification Panel	Ear Nose & Throat
Device Class	Unclassified

Predicate Device:

Predicate Device	System 2000 by Micromedical
Manufacturer	Micromedical Technologies inc
510(k) No.	K922037
Date Cleared	10/26/1992

Device Description

The Orion is a rotary chair designed to assess the Vestibular Ocular Reflex (VOR).

Orion rotary chair includes these three variants

- Orion Reclining
- Orion Auto Traverse
- Orion Comprehensive

The Orion is considered an accessory to vestibular examination system software designated VisualEyes 525 and VisualEyes 515 manufactured by Interacoustics (FDA 510(k) K200534).

The Orion is an update of the System 2000 by Micromedical ((FDA 510(k) ID K922037).

Variant description	**Orion** Reclining	The chair allows you to carry out all tests in a minimum of space. In addition to rotation tests, it reclines precisely to 30 degrees for caloric testing with easy access to both ears. It also reclines completely to act as an exam table for positional and Dix-Hallpike tests.
	Orion Auto Traverse	This chair features include a dark room enclosure for eyes uncovered recording, an XY laser projector for ocularmotor testing in both horizontal and vertical directions, and a full-field optokinetic drum that projects moving stripes on the booth wall. Also for ocularmotor testing. Advanced features include the ability to shift the center of rotation off-axis and to perform a dynamic subjective visual vertical test.
	Orion Comprehensive	This chair features a dark room enclosure for eyes uncovered recording, an XY laser projector for testing in both horizontal and vertical directions, a static subjective visual vertical test, and a full-field optokinetic drum that projects stripes from the floor to the ceiling. Also for ocularmotor testing.
Indications for use	The Orion rotary chair is an optional accessory for VisualEyes 525/ VisualEyes 515 eye movement recording systems. 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.	
Technological characteristics	The Technological Characteristics are the same as the predicate device. See Substantial Equivalence table below for characteristics.	

Substantial Equivalence

Interacoustics A/S have chosen to compare the Orion Rotational Vestibular Chair with the Micromedical Technologies System 2000 -Rotational Vestibular Chair for the following reasons.

- Orion is an updated version of the System 2000
- The predicate systems have the same medical purpose
- System 2000 has obtained FDA 510(k) clearance
- Both new device and predicate device comes in the same 3 model variants
    - Reclining
    - Auto Traverse
    - Comprehensive

Both Orion and System 2000 are supported by the software called VisualEyes 515/525.

Comparison table

Orion – Rotational Vestibular Chair
Versus
System 2000 - Rotational Vestibular Chair

Description	Orion Model: Reclining	System 2000 Model: Reclining	Equivalence
Intended use	The Orion rotary chair is an optional accessory for VisualEyes 525/ VisualEyes 515 eye movement recording systems	The System 2000 rotary chair is an optional accessory for eye movement recording systems	Same
Software to support	VisualEyes 515/525	VisualEyes 515/525 and Spectrum	Same (Spectrum is the replaced software) See also “Equivalent discussions (Software)” below this table
Chair and Controller	yes	yes	Same
Video Goggle connector	yes USB	yes Firewire	Equivalent – USB and firewire are communication protocols
Patient Weight Maximum	350 lbs (158kilo)	350 lbs (158kilo)	Same
VOR, VVOR, VFX	yes .01-.64 Hz	yes .01-.64 Hz	Same
Step tests	max 200	max 200	Same
VOR Analysis	yes	yes	Same
Equipment cart	yes	yes	Same
Ocularmotor Tests	yes	yes	Same

VORTEQ/VHIT/DVA	Option	Option	Same
EOG	Option	Option	Same
Mechanical Foot Brake	Electric Lock	yes	Equivalent – please refer to " Equivalent discussions (Mechanical Foot Brake)" below this table
Sinusoidal Frequency	0.01 to 0.64 Hz	0.01 to 0.64 Hz	Same
Step Velocity (max)	200 deg/sec	200 deg/sec	Same
Acceleration (max)	100 deg/sec2	100 deg/sec2	Same

Equivalent discussions (Software)
The evaluation of the VisualEyes 515/525 compared to Spectrum was included in the 510(k) submission cleared under K163149. The evaluation was done for the System 2000 rotational chair. The Orion chair hardware equivalency was established by setting tests in VisualEyes 515/525 to certain parameters and then physically measuring the chair performance.

Equivalent discussions (Mechanical Foot Brake)
The ORION Reclining Chair implements an electronic lock. This function is designed to place the chair into an immobile state in order to ensure patient safety when seating and/or disembarking the patient from the reclining chair. It is also used to keep the chair immobile during the VNG test battery. The lock chair function is only made available prior to the test and cannot be activated during the testing procedure. This will automatically be switched off when performing a rotational chair test.

The System 2000 Reclining chair does not have an electronic braking system. A manual foot brake is found on the side of the chair drum. The operator should apply the brake to keep the chair in place for patient entry and VNG testing. When reclining the chair for Dix Hallpike, Positional, and Caloric tests, the foot brake should be released in order to rotate the chair if needed due to space constraints. The foot brake should then be reapplied when the chair is reclined to the appropriate position to keep the chair from rotating during the test.
Interacoustics A/S appraise that the function of the Mechanical Foot Brake and the electric lock is essential equivalent.

Description	**Orion** **Model: Auto Traverse / Comprehensive**	**System 2000** **Model: Auto Traverse / Comprehensive**	**Equivalence**
Intended use	The Orion rotary chair is an optional	The System 2000 rotary chair is an optional	Same

	accessory for VisualEyes 525/ VisualEyes 515 eye movement recording systems	accessory for eye movement recording systems	
Software to support	VisualEyes 515/525	Spectrum	Equivalent – please refer to Software Equivalent discussion just above
Chair and Controller	yes	yes	Equivalent – the controller for Orion is inside the Chair base, whereas for System 2000 it is a separate unit.
Video Goggle Connector	yes USB	yes FireWire	Equivalent – USB and firewire are communication protocols
Patient Weight Maximum	400 lbs	400 lbs	Same
VOR, VVOR, VFX	yes, .01 - .64 Hz	yes .01-.64 Hz	Same
Step tests	Yes	Yes	Same
VOR Analysis	yes	yes	Same
Equipment cart	yes	yes	Same
Ocularmotor Tests	yes	yes	Same
X-Y laser	yes	yes	Same
Optokinetic projector	yes	yes	Same
Chair enclosure	yes	yes	Same
Subjective Visual Vertical	yes	yes	Same
Auto-Traverse Centrifuge	yes	yes	Same
VORTEQ/VHIT/DVA	Option	Option	Same
EOG	Option	Option	Same
Mechanical Foot Brake	no	no	Same
Sinusoidal Frequency	0.01 to 0.64 Hz	0.01 to 0.64 Hz	Same
Step Velocity (max)	350 deg/sec	300 deg/sec	Equivalent – because typical Step Velocity test parameters do not exceed 180 d/s irrespective of the maximum constant velocity capability of the chair. SVV test parameters use only 300 d/s for the test.

Acceleration (max)	200 deg/sec2	200 deg/sec2	Same
Lateral movement	-7cm to +7cm	-7cm to +7cm	Same
Lateral movement speed	0.8 cm/sec	1 cm/sec	Equivalent – because the speed to go offset is not a critical parameter. The lateral offset from on-axis rotation is what controls the stimulation of Otolith organs and not the speed to attain this offset.

Performance Tests
Interacoustics A/S appraise that there are only minor updates and changes to the devices and that the safety and efficiency are essential the same.

Interacoustics A/S have performed comparisons between the updated revision of Orion chairs and the predicate device. All these activities, testing and validation show that Orion chairs performs as specified and are safe and effective.

Clinical tests
No clinical tests were performed. Interacoustics A/S have performed comparisons between the Orion chairs and the predicate device. These activities, testing and validation show that Orion chairs perform as specified and are safe and effective.

Discussion of differences
Interacoustics A/S did not find any essential or major differences between the predicate and subject devices. Any deviations between Orion chairs and predicate device are appraised to have no impact on the safety and effectiveness of the device.

Conclusion
Interacoustics A/S have compared key issues for the Orion chairs and the predicate device. Interacoustics A/S have performed a comparison validation between Orion chairs and the predicate device.

Based upon non-clinical and clinical performance testing, the Orion chairs were found to have a safety and effectiveness profile that is comparable to the predicate device. Therefore, Interacoustics A/S has demonstrated that the Orion chairs are substantially equivalent to the stated predicate device.