May 27, 2020

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

Re: K192652
Trade/Device Name: TRV
Regulation Number: 21 CFR N/A
Regulation Name: N/A
Regulatory Class: Class II
Product Code: LXV
Dated: Not dated
Received: April 29, 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 Michael J. Ryan
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)*
K192652

Device Name
TRV

Indications for Use *(Describe)*
The TRV is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo.

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

TRV – Multi-axial chair

Submitter Information:

Company Name	Interacoustics A/S
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Contact Person	Erik Nielsen, Director, Regulatory & Compliance
Date Summary Prepared	April 17, 2020

Device Identification:

Trade Name	TRV
Common Name	Multi-axial chair
Classification Name	Apparatus, vestibular analysis
Product Code	LXV
Classification Panel	Ear Nose & Throat
Device Class	Unclassified

Predicate Device:

Predicate Device	Epley Omniax™
Manufacturer	Vesticon inc
510(k) No.	K071973
Date Cleared	06/20/2008

Device description

The TRV is a multi-axial chair that can rotate 360° around both the horizontal and vertical axes. With the patient secured by a four-point harness, a head mount, a leg strap, and shoulder pads, an examiner is able to rotate the patient around the plane of each of the 6 semicircular canals and hold the patient in any position for detailed examination of the semicircular canals.

The rehabilitation of patients diagnosed with positional vertigo commonly involves traditional maneuvers such as the Epley, Semont, etc. These maneuvers can be performed efficiently and safely with the TRV chair. Kinetic energy can be added for specific maneuvers by driving the main arm of the TRV chair against a hydraulic stop in each sequence in the maneuver. This added kinetic energy accelerates the movement of the smaller otoconia.

The TRV chair is manually handled by the healthcare professional. The axes of rotation are lockable in preset positions. The primary axis has a battery-powered electromagnetic lock controlled by a footswitch and the secondary axis is manually locked with a mechanical lever. A mechanical system with an adjustable counterweight ensures that the weight of the chair and the patient are balanced during the maneuvers.

Healthcare professionals may use the TRV in combination with videonystagmography goggles to detect positional induced nystagmus while moving the patient through a series of positions

Indications for Use

The TRV is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo.

Technological characteristics

The Technological Characteristics are the same as the predicate device. See Substantial Equivalence table below for characteristics.

Substantial Equivalence

Precise, multiaxial patient positioning for the analysis of nystagmus and the application of maneuvers used to treat vestibular disorders is the technological principal for both the subject and predicate devices.

At a high level, the subject and predicate devices are based on the same technological elements as presented in the table below.

The information regarding the videonystagmography system of the Epley Omniax™ has not been included as this function is not an integral part of the TRV.

	TRV	**Epley Omniax™**	**SE Comparison**
Indications for Use	The TRV is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo.	The Epley Omniax™ is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo.	Same
Use environment	In a medical practice	In a medical practice	Same
User	Trained healthcare professional	Trained healthcare professional	Same

Patient population	Patients presenting with imbalance, unsteadiness or dizziness symptoms suspected of originating from dislocated otoconia in one or more of the semicircular canals in the inner ear.	Patients presenting with imbalance, unsteadiness or dizziness symptoms suspected of originating from dislocated otoconia in one or more of the semicircular canals in the inner ear.	Same
Test options			
Video recording	Yes	Yes	Same
Nystagmus analysis	Yes	Yes	Same
Oculomotor tests	Yes	Yes	Same
Session logging	Yes	Yes	Same
Positional tests	Yes	Yes	Substantial equivalent Discussed below
Maneuvers			
Canalith repositioning (Epley)	Canalith repositioning (Epley) for Posterior semi-circular canal (PSC) BPPV	Pre-set protocol "Canalith repositioning"	Substantial equivalent Both devices can perform same maneuver
Semont	Canalith repositioning for PSC BPPV	Customized protocol using the Freestyle tab	Substantial equivalent Both devices can perform same maneuver
Lorin	Canalith repositioning for Anterior semi-circular canal (ASC) BPPV	Customized protocol using the Freestyle tab	Substantial equivalent Both devices can perform same maneuver
BBQ Roll Left HSC	Canalith repositioning for Horizontal semi-circular canal (HSC) BPPV canalithiasis, Left side	Pre-set protocol "3/4 Barrel roll" – canalithiasis Left	Substantial equivalent Both devices can perform same maneuver
BBQ Roll Right HSC	Canalith repositioning for Horizontal semi-circular canal (HSC) BPPV canalithiasis, Right side	Pre-set protocol "3/4 Barrel roll" – canalithiasis Right	Substantial equivalent Both devices can perform same maneuver
BBQ Roll Left HSC	Canalith repositioning for Horizontal semi-circular canal (HSC) BPPV cupulolithiasis, Left side	Pre-set protocol "3/4 Barrel roll" – cupulolithiasis Left	Substantial equivalent Both devices can perform same maneuver
BBQ Roll Right HSC	Canalith repositioning for Horizontal semi-circular canal (HSC) BPPV cupulolithiasis, Right side	Pre-set protocol "3/4 Barrel roll" – cupulolithiasis Right	Substantial equivalent Both devices can perform same maneuver
360° Back Flip "incremental"	360° Back Flip "incremental"	Pre-set protocol 360° Back Flip "incremental"	Substantial equivalent Both devices can perform same maneuver

360° Back Flip "continuous"	360° Back Flip carried out in slow, continuous sweep	Pre-set protocol 360° Back Flip "continuous"	Substantial equivalent Both devices can perform same maneuver
360° Forward Flip	360° Forward Flip	Pre-set protocol 360° Forward Flip	Substantial equivalent Both devices can perform same maneuver
Technical			
Dimensions	Weight: 640 kg Height: 1.9 m Depth: 1.6 m Width: 1.2 m	Weight: 372 kg Height: 2.1 m Depth: 2.0 m Width: 2.3 m	The TRV is slightly smaller in size and heavier than the predicate device. This difference does not raise new questions of safety and effectiveness.
Movement range	2 axes, 360° each: - Primary axis is a roll movement with the patient in the load position. - Secondary axis is a yaw movement with the patient in the load position.	2 axes, 360° each: - Alpha axis is a roll movement with the patient in the load position. - Beta axis is a yaw movement with the patient in the load position.	The range of motion is the same for both devices.
Power supply	The TRV chair is equipped with a 24V rechargeable battery that powers the magnetic lock for the primary frame (Linak BAJ1 (24 V DC, 2,9 Ah)). A wall-mounted battery charger is also provided (Linak, CHJ2).	Mains power supply: Voltage input 120V/240V (switchable) at 50-60Hz Current rating: 6A @120V, 3A @ 240V Fusing: 8A @120V, 4A @ 240V Isolation from main power designed to meet UL/cUL 2601	Both devices have passed electrical security testing according to IEC 60601-1 and EMC testing according to IEC 60601-1-2. The differences in the energy source do not raise different questions of safety and effectiveness and are supported by testing

Positional tests discussion

The multi-axial positioning has been evaluated comparing the positions available from the TRV and the Omniax. Interacoustics has found that the positionings enables the same maneuvers and both devices offer multi-axial patient positioning with rotation around 2 axes.

Discussion of differences

Interacoustics did not find any essential or major differences between the devices.

Performance data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the TRV. The device complies with the IEC 60601-1 for electrical safety and the IEC 60601-1-2 standard for EMC.

Mechanical testing

To evaluate the worst-case stress loads and simulate device-use lifetime and demonstrate long-term safety of the TRV, the independent test institute Danish Technological Institute has tested the TRV based on the agreed test criteria from Interacoustics. After the testing of the TRV, the wear observed is considered not to have any effect on the safety on the patients or operator of the TRV.

Animal and clinical studies

No animal or clinical testing was required to demonstrate the substantial equivalence of this device to its predicate, nor its safety and effectiveness.

Conclusion

Based on its intended use, design principles, and technological characteristics, the TRV was found to be as safe, as effective, and performs comparably to the predicate device.

The technological differences identified do not raise new questions of safety and effectiveness as the non- clinical data support the safety of the device and demonstrate that the TRV performs as intended in the specified use conditions.