K130795

510(K) SUMMARY

JUN 2 0 2013

Titan
Titan with TEOAE440

Submitter Information:

Company Name	Interacoustics A/S
Address	Drejervaenget 8 Assens, DK-5610, Denmark
Phone	+45 6371 3555
Fax	+45 6371 3522
e-mail	info@interacoustics.com
Contact Person	Erik Nielsen, Director, Quality and Regulatory Affairs
Date Summary Prepared	Marts 21 2013

Device Identification:

Trade Name	Titan
Common Name	Audiometer
Classification Name	Otoacoustic emission device
Product Code	EWO
Panel	Ear Nose & Throat
Device Class	Class II (According to 21CFR874.1050)

Predicate Devices:

Substantial Equivalence 1	
Predicate Device	Titan with DPOAE440
Manufacturer	Interacoustics
510(k) No.	K103760
Date Cleared	05/05/2011
Substantial Equivalence 2	
Predicate Device	Eclipse with TEOAE25
Manufacturer	Interacoustics
510(k) No.	K052562
Date Cleared	12/23/2005

Interacoustics

Device Description

The instrument is multi platform audiometric equipment used for various testing of middle ear, inner ear and brainstem abnormalities. This submission is only about OAE measurements of otoacoustic emissions in the human inner ear evoked by acoustic probe pulses. (TEOAE in accordance with IEC60645-6:2009)

The Titan also has a measurement function of otoacoustic emissions in the human inner ear evoked by acoustic probe tones (DPOAE). This functionality is already cleared by FDA 510(k) premarket notification K103760 (05/05/2011)

The Titan OAE test generates an acoustic stimulus in the ear canal at a moderate intensity level. The stimulus vibrates a thin membrane in the cochlear, and activates the outer hair cells located on the membrane. This activation is propagated back through the middle ear as sound into the ear canal. Microphone(s) detects OAE-related sound. Principles are identical for both tone and pulse stimuli.

The instrument has screening and diagnostic functionality of TEOAE (according to IEC 60645-6), which is license dependent. For screening purpose a protocol with Pass-Refer criteria can be set up by the user.

Indications for Use

The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions.
The target population for Titan with TEOAE440 includes all ages.

Intended operator

The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.

Technological Characteristics

Titan consists of a handheld unit named Titan, Titan Cradle and PC software (Titan Suite, Titan modules/ Titan Applications). The measurements are controlled by the handheld unit. A license system makes it possible within each configuration to select which functionality the user wants to be incorporated in the system.

A connection box (shoulder box) enables different types of accessories to be connected to the platform (depending on the module)

For measuring Transient Evoked OtoAcoustic Emissions (TEOAEs) a probe is placed into the ear canal. A stimulus of short duration (broad band click) is presented into the ear (typically with at intensity of 80dB peSPL). Within a normal functioning cochlea the outer hair cells will become active and produce low intensity tones that travel back out of the ear. The emissions that can be recorded appear in the same frequency range and are recorded following each presentation of the transient stimulation. Being able to measure a significant amount of TEOAEs indicates a normal or close to normal outer hair cell function and is mostly used as a screening for hearing impairment. When no TEOAEs are measured, a priori no conclusion can be made and further diagnostics would be recommended.

The instrument meets the requirements from the international standard for OAE measurements IEC 60645-6.

Nonclinical tests summary

Design verification and validation were performed according to current standards for OAE (otoacoustics emmissions) to assure Titan with TEOAE440 meets its performance specifications.

Clinical tests

No clinical tests were performed, but based on the fulfilment of the international standards for OAE, and the comparison to predicate devices we trust the device is safe and effective without further clinical tests.

Conclusion

We trust that the verification and validation reports and risk analysis together with the comparisons provided in this 510(k) supports the conclusion that the Titan With TEOAE is safe and effective and that is demonstrates that the Titan with TEOAE440 is substantially equivalent to the marketed predictive devices.

Comparison table for Titan with TEOAE440 and Titan with DPAOE440

Description	Titan with DPOAE440	Titan with TEOAE440	Equivalence
Type	Audiometer	Audiometer	Same
Regulation Number	21 CFR 874.1050 (otoacoustic emission device)	21 CFR 874.1050 (otoacoustic emission device)	Same
Classification Product Code	EWO	EWO	Same
Regulatory Class	Class II	Class II	Same
Indications for use	The Titan with DPOAE44O is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Titan with DPOAE44O includes all ages.	The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Titan with TEOAE440 includes all ages.	Different See discussion below this table The difference is the subject of this 510(k)
Target population	The devices are suitable for all populations including new-born infants	The devices are suitable for all populations including new-born infants	Same
Intended user	The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	Same
Database			
	Supported by Interacoustics OtoAccess™ database.	Supported by Interacoustics OtoAccess™ database.	Same
	Operating under NOAH is possible, using IA NOAHLink.	Operating under NOAH is possible, using IA NOAHLink.	Same

Discussion Titan with TEOAE440 versus Titan with DPOAE440

We have chosen not to compare the physical data (e.g. weight, dimensions and similar technical performance) as the Titan with TEOAE440 is physically and technically identical with previous versions of the Titan unit. There are no mechanical or hardware distinctions.

There are basically two types of evoked otoacoustic emissions: Transient Evoked (TE) and Distortion Product (DP). They both have an identical medical purpose. Both otoacoustic emission (OAE) tests determine cochlear status, specifically hair cell function used for evaluation of ear disorders. The difference is the technology. DPOAE acoustic signals are generated in the inner ear during stimulation with two pure tones. TEOAE acoustic signals are emitted by the inner ear after stimulation with a stimulus of short duration. TEOAEs seems slightly better identifying hearing loss at 500 and 1000Hz that DPOAEs are better at identifying hearing loss at 4000Hz. TEOAE and DPOAE identify hearing loss with same accuracy at 2000Hz. The purpose of extending the Titan with TEOAE capability is to provide a full range of test opportunity.

Based on the comparison between the two versions of Titan with OAE capability we appraised they are fully substantial equivalent.

Comparison table for Titan with TEOAE440 and Eclipse with TEOAE25

Description	Eclipse with TEOAE25	Titan with TEOAE440	Equivalence
Type	Audiometer	Audiometer	Same
Regulation Number	21 CFR 874.1050 (otoacoustic emission device)	21 CFR 874.1050 (otoacoustic emission device)	Same
Classification Product Code	EWO	EWO	Same
Regulatory Class	Class II	Class II	Same
Indications for use	The Interacoustics TEOAE25 system is intended for determining Cochlear function using Transient Evoked Otoaccoustic Emission click stimuli.	The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Titan with TEOAE440 includes all ages.	Similar The indications for use is intended to cover the same clinical purpose as TEOAE25, but the wording is just aligned with the indications for use defined for Titan with DPOAE440
Target population	The devices are suitable for all populations including new-born infants	The devices are suitable for all populations including new-born infants	Same
Intended user	The Eclipse System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	Same
Stimulus:			
Frequency Range	400 to 4000 Hz	500 to 5500Hz	Similar Both fulfils the requirements from IEC 60645-6
Stimuli type	Non-Linear and Linear Short duration signal (Click) According to IEC 60645-3	Non-Linear and Linear Short duration signal (Click) According to IEC 60645-3	Same

Description	Eclipse with TEOAE25	Titan with TEOAE440	Equivalence
Level	50 to 90 dB SPL	30 to 90 dB peSPL	Similar The level range (30-90) is a requirement From IEC60645-6 clause 5.1.4.2 for type 1 instruments
Level Step	1 dB SPL	1 dB SPL	Same
Transducer	Dedicated TEOAE25 probe	Dedicated IOW Probe	Similar Both are dedicated probes for different systems
Probe detection	Auto detection	Auto detection	Same
Recording			
A/D Resolution	16 bit	24 bit	Similar The TEOAE440 offers newer technology with higher resolution (24bit)
Artifact Reject System	+25 –> +55 dB SPL or off.	0 -> +60 dB SPL or off	Similar The TEOAE440 offers newer technology and has increased the artifact setting range.
Automatic test with display of PASS-REFER	Yes	Yes	Similar. See discussion below

Discussion Titan with TEOAE440 versus Eclipse TEOAE25

The Titan with TEOAE440 and Eclipse with TEOAE25 share the same otoacoustic emission method. The otoacoustic emissions are emitted from the inner ear after stimulation with a stimulus of short duration. The stimulus is in accordance with the international standard IEC 60645-3 for both instruments. They differ slightly based on the technology. As the Eclipse has older technology the Titan with TEOAE440 has better technical characteristics. This was also concluded though the validation of the Titan with TEOAE440. Beside that we trust that the two devices are substantial equivalence based on the comparison above.

Both instrument types have Automatic test with display of PASS-REFER. The automatic test is in accordance with IEC60645-6 clause 4, clause 5.3.6 and 5.3.8.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 20, 2013

Interacoustics A/S
c/o Mr. Erik Nielsen
Director, Quality and Regulatory Affairs
8 Drejervaenget
Assens
Denmark, DK-5610

Re: K130795
Trade/Device Name: Titan with TEOAE440
Regulation Number: 21 CFR 874.1050
Regulation Name: Otoacoustic Emissions Device
Regulatory Class: Class II
Product Code: EWO
Dated: March 22, 2013
Received: May 22, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use

Applicant: Interacoustics A/S

510(k) Number (if known): K130795

Device Name: Titan with TEOAE440,

Indications for Use:
The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Titan with TEOAE440 includes all ages.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Eric A. Mann -S

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leading diagnostic solutions