MAY - 5 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Titan
Titan with DPOAE440
Titan with ABRIS440

SUBMITTER INFORMATION

Company Name	Interacoustics A/S
Company Address	Drejervaenget 8 Assens, DK-5610, Denmark
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Contact Person	Erik Nielsen, Director, Quality and Regulatory Affairs
Date Summary Prepared	Apr. 28 2011

DEVICE IDENTIFICATION

Trade Name	Titan
Common Name	Audiometric equipment
Classification Name	Otoacoustic emission device, Evoked response auditory stimulator and measurements
Product Code	EWO / GWJ
Panel	Ear Nose & Throat / Neurology
Device Class	Class II

SUBSTANTIAL EQUIVALENCE (TITAN WITH DPOAE440)

Predicate Device	DPOAE20 (Eclipse)
Manufacturer	Interacoustics
510(k) No.	K060539
Date Cleared	05/30/2006

SUBSTANTIAL EQUIVALENCE (TITAN WITH ABRIS440)

Predicate Device	Maico MB 11
Manufacturer	MAICO
510(k) No.	K082035
Date Cleared	01/29/2009

Device Description
The instrument is audiometric equipment used for testing middle ear, inner ear and brainstem abnormalities.

The Titan is a combination of:
- Audiometric device for measurement of aural acoustic impedance (IMP) (Cleared under K083861)
- Audiometric device for measurement of otoacoustic emissions (OAE)
- Audiometric device for measurement of auditory brainstem responses (ABR)

The Titan can have one of three functions depending on license:

The Titan IMP test is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear.

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 sounds.

The Titan ABR test produces a short acoustic stimulus and measures via cutaneous electrodes the auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The test uses an automatic detection algorithm to determine if an ABR is evoked in response to the short acoustic stimulus. The output of the device is either PASS (ABR detected) or REFER (ABR is not detected).

The Titan with DPOAE440 is intended as clinical audiometer.
The Titan with ABRIS440 is intended as a screener audiometer.

Indications for Use
The Titan with DPOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Titan with DPOAE440 includes all ages.

The Titan with ABRIS440 is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem.The target population for Titan with ABRIS440 is newborns.

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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)
The Titan platform can connect to PC software via a Bluetooth connection.

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Comparison Titan with ABRIS440 and predicate device

Description	Maico, MB 11	Titan with ABRIS 440	Equivalence
Indications for use	The Maico MB 11 with BERAphone and the MB 11 Standard are intended to generate evoked auditory brainstem response (ABR) - based measurements for newborn hearing screening, providing a PASS/REFER result.	The Titan with ABRIS440 is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem.	Similar The wording is just a little different
Target population	Newborns	Newborns	Same
Intended user	The User does not require special technical skills or interpretation of the results.	The User does not require special technical skills or interpretation of the results.	Same
Anatomical sites	Examination of Ear and hearing nerves	Examination of Ear and hearing nerves	Same
Safety standards	IEC 60601-1	IEC 60601-1	Same
Performance standard	IEC 60645-7 (Type 2)	IEC 60645-7 (Type 2)	Same
Device Type	Screening device (PASS/REFER) result	Screening device (PASS/REFER) result	Same
System Configuration	1 -channel ABR system operated through a base unit connected via a USB port to any standard computer (Laptop Computer recommended)	1 -channel ABR system operated through a handheld base unit. The base unit can be operated stand alone or PC controlled through USB or Bluetooth.	Similar The only different is that Titan can work as stand alone
Display information	Testing sequence along with current EEG parameters (number of sweeps, number of artifacts, SNR, and artifact rejection system setting)	PASS/REFER status, indicated with value between 0 and 100% where 100% indicates a pass. EEG peak or RMS value, rejection status, residual noise and what transducer(s) are detected.	Similar Some minor differences in displayed information
Electrode quality check	YES	YES	Same
Impedance Test (Quality control)	Indicator in three levels. Red: above 10kOhm Yellow: between 10 & 8kOhm Green: below 8kOhm	Before recording: Electrode impedance is measured if they are above 10kOhm, below 10 kOhm or below 3 kOhm.	Similar The difference in the mid range is due to measurement frequencies

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Description	Maico, MB 11	Titan with ABRIS 440	Equivalence
			and has influence on the results. The Titan may require a little more carefulness while placing electrodes.
Binaural screening	YES	YES	Same
Pre-amplifier channels	1	1	Same
Stimulus	Chirps	Chirps	Same Please refer to comparison between MB-11 and ABRIS440 in attachment 12-E
Pre-amplifier Gain	86 dB	64 dB	Similar Depends on amplifier characteristics as CMMR and SN ratio. Have no influence on measuring results.
Filtering	HW HP 30Hz filters of 1st order	Two HW HP filters of 1st order: Cut-off frequencies 7Hz and 45Hz	Similar Both look at frequencies above 80Hz and at that frequency the response from the two filters are identical. The basic purpose of the filters

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Description	Maico, MB 11	Titan with ABRIS 440	Equivalence
			are to eliminate DC components
Masking	None	None	Same
Transducers	BERAphone TDH39 EAR 3A Insert phones	Titan Probe TDH39 EAR 3A Insert phones	Similar The Titan probe is a dedicated probe for Titan as the BERAphone is a dedicated probe for MB-11
Stimulus rate	92.5/s	90/s	Similar
Screening level	35dBHL	35dBHL	Same
Screening measurement	180 seconds	180 seconds	Same

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Comparison Titan with DPOAE440 and predicate device

	DPOAE20 (Predicate)	DPOAE440 (New)	Comments
Indications for use	The Interacoustics DPOAE20 system is for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emission tone stimuli. The presence of Otoacoustic emissions suggests normal outer hair cell function within cochlea, which in turn suggests normal hearing. OAEs are recorded using an OAE probe which is placed in the ear canal. The OAE response from the ear is recorded and processed by the Eclipse and the DPOAE2O software and then displayed on the computer screen for evaluation.	The Titan with DPOAE440 is intended for use in the diagnostic audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions.	Similar The wording is just a little different
Target population	The patient group includes all ages	The patient group includes all ages	Same
Intended user	Ear, Nose, and Throat doctors, Neurology specialists, Audiologist and other health- professionals concerned with measuring auditory functions.	The Titan is designed to be used only by skilled personnel such as audiologists, ENT surgeons, and doctors, hearing healthcare professionals or personnel with similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.	Same
Evaluation method	DPOAE	DPOAE	Same
Safety standard	IEC 60601-1	IEC 60601-1	Same
EMC standard	IEC 60601-1-2	IEC 60601-1-2	Same
Performance standard	IEC 60645-6 (Type 2)	IEC 60645-6 (Type 2)	Same

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	DPOAE20 (Predicate)	DPOAE440 (New)	Comments
Test signals	IEC 60645-1/ANSI S3.6 , IEC 60645-3	IEC 60645-1/ANSI S3.6 , IEC 60645-3	Same
Stimulus:			
Frequency Range	500-8000 Hz	500 to 10000 Hz	Similar The DPOAE has an extended range. This is a technical improvement due to better technology and probes.
Frequency Step	50 Hz	25 Hz	Similar A technical better resolution is possible due to better technology.
Level	30-75 dB SPL (70 dB above 6kHz)	30 to 80 dB SPL (75 dB SPL for 6kHz and 65 dB SPL for 8kHz and 10kHz)	Similar The DPOAE has an extended range. This is a technical improvement due to better technique and probes.
Level Step	1 dB SPL	1 dB SPL	Same
Transducer	Dedicated DPOAE20/TEOAE25 probe	Dedicated IOW Probe	Similar New transducer due to the hardware design of Titan is different from DPOAE20 hardware. The transducer has the same characteristics as the predicate. The transducer is not new compared to the previous version of Titan cleared under K083861
Probe detection	None	Auto detection	Different The probe unit has build-in memory for all probe relevant calibration values.
Recording			
Analysis time	Minimum 2 sec to unlimited test time.	Minimum 2 seconds to unlimited time	
A/D Resolution	16 bit, 7.3 Hz resolution	24 bit, 5.38 Hz resolution	Similar Better resolution due to better technology used

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	DPOAE20 (Predicate)	DPOAE440 (New)	Comments
Artifact Reject System	-30 –> +30 dB SPL or off.	-30 to +30 dB SPL or off	Same
Stimulus Tolerance	Adjustable between 1 and 10 dB	Adjustable between 1 and 10 dB	Same
SNR Criteria	Adjustable between 1 and 20 dB	Adjustable between 3 and 25 dB	Similar The limits has be adjusted to better fit to real world practice. This givers higher evidence for response. (1 dB is in fact too small to use as criteria)
Probe check window	256 points frequency response of the ear canal due to a click stimulus presented with a rate of 100 Hz at 80 dB SPL	1024 points frequency response of the ear canal due to a click stimulus	Similar Better resolution due to better technology used
DP-Response window	4096 points frequency response	4096 points frequency response	Same
Display			
General Display gain	Applicable during testing	Applicable during testing	Same
Display	Stimulus level and type	Stimulus level and type, Basic and advanced view	Similar A simpler (basic) view has been introduces
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

Test summary

The Titan was tested according to current standards for OAE and ABR and was found to conform to the standards. No clinical tests were performed, but based on the fulfillment of the international standards for OAE and ABR, and the comparison to predicate devices we believe the device is safe and effective.

Conclusion

We have compared the intended use and performance characteristics with the predicate devices. The Titan was tested according to current standards and the differences found between the devices were related to functionality, not in relation to safety and efficiency. The Titan conforms to the current standards.

The Titan with DPOAE440 and Titan with ABRIS440 were found to be substantially equivalent to the predicate devices in technological characteristics and indications for use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

MAY - 5 2011

Re: K103760
Trade/Device Name: Titan with ABRIS440 and Titan with DPOAE440
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ, EWO
Dated: April 7, 2011
Received: April 12, 2011

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103760

Indications for Use

Applicant: Interacoustics A/S

510(k) Number (if known): K103760

Device Name: Titan with DPOAE440,
Titan with ABRIS440

Indications for Use:
The Titan with DPOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Titan with DPOAE440 includes all ages.

The Titan with ABRIS440 is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem.The target population for Titan with ABRIS440 is newborns.

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

Prescription Use X
(Per 21 CFR

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103760