K121847

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Titan
IMP440 WBT

NOV 29 2012

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	June. 21 2012

DEVICE IDENTIFICATION

Trade Name	Titan
Common Name	Audiometric equipment.
Classification Name	Tester, Auditory Impedance / Evoked response auditory stimulator
Product Code	ETY / GWJ
Panel	Ear Nose & Throat / Neurology
Device Class	Class II

SUBSTANTIAL EQUIVALENCE (TITAN WITH IMP440)

Predicate Device	Titan with IMP440
Manufacturer	Interacoustics
510(k) No.	K083861
Date Cleared	04/09/2006

SUBSTANTIAL EQUIVALENCE (MIMOSA HEARID)

Predicate Device	HEARID WIDEBAND MIDDLE EAR POWER ANALYZER
Manufacturer	MIMOSA ACOUSTICS, INC
510(k) No.	K053216
Date Cleared	02/10/2006

Description of device

The instrument is audiometric equipment used for measuring aural acoustic impedance and admittance (According to ANSI S3.39).

The Titan is a platform with multi functions depending of licensing. The license function for this submission is IMP440 (IMP) for measurement of aural acoustic impedance and admittance.

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 IMP test function is already cleared by FDA 510(k) premarket notification K083861 (04/09/2009)

The instrument is a diagnostic/clinical instrument (as defined in IEC60645-5), but provides normative data for guidance.

Titan consists of a handheld unit named Titan, Titan Cradle (cleared by FDA 510(k) premarket notification K083861) and PC software (Titan Suite/IMP440). The measurements are controlled by the handheld unit.

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

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

Indications for Use

The Titan Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflexes.

The Titan Impedance System measures various acoustic properties of the ear, namely power reflectance, power absorption, transmittance, reflectance group delay, complex acoustic impedance and admittance, and equivalent ear canal volume. These measures allow the evaluation of the functional condition of the middle and outer ear.

The Titan Impedance System is suitable for all populations including new-born infants.

The Titan Impedance 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 device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

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.

For measuring acoustic properties of the middle ear a probe is placed into the ear canal. The probe presents a calibrated tone or click sound into the ear canal and by recording the intensity and phase of the remaining tone or click in the ear canal it can be derived how much of the sound is absorbed by or transferred into the ear. Most common measures are:

- A tympanogram, in which the compliance/absorbance is measured as function of the presented frequencies and pressure in the ear canal;
- An acoustic reflex, in which the compliance/absorbance is measured over time as function of the presented frequencies while an acoustic activator is presented that above certain intensity is expected to cause a contraction of the stapedius muscle which in return is expected to cause a change in the compliance/absorbance of the ear.

The levels of the tonal and click sounds are to be calibrated in an artificial ear according to peak to peak equivalent signal level principles in IEC 60645-3

Titan with IMP440 WBT is IEC 60645-5/ANSI S3.39, Type 1 (Diagnostic/Clinical) acoustic impedance instrument

Comparison table for Titan with IMP440 and Titan IMP440 WBT

Description	Titan with IMP440	Titan with IMP440 WBT	Equivalence
Indications for use	The Titan Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflexes.	The Titan Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflexes. The Titan Impedance System measures various acoustic properties of the ear, namely power reflectance, power absorption, transmittance, reflectance group delay, complex acoustic impedance and admittance, and equivalent ear canal volume. These measures allow the evaluation of the functional condition of the middle and outer ear. The Titan Impedance System is suitable for all populations including new-born infants. The Titan Impedance 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 device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.	Same The first paragraph for Titan IMP440 WBT is identical with the previous version of the Titan with IMP440 The addition of subsequent paragraphs 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 devices are to be used by trained personnel only.	The devices are to be used by trained personnel only.	Same

Comparison table for Titan with IMP440 WBT and Mimosa HearID

	HearID (Predicate)	Titan IMP440 WBT	Comments
Type	Audiometric equipment	Audiometric equipment	Same
Indications for use	The intended use of the HearID-wbMEPA Middle Ear Power Analyzer is to characterize the middle ear status and to assist in diagnosing middle ear pathologies. The HearID-wbMEPA system measures various acoustic properties of the ear, namely power reflectance, power absorption, transmittance, reflectance group delay, complex acoustic impedance and admittance, and equivalent ear canal volume. These measures allow the evaluation of the functional condition of the middle and outer ear. The devices are suitable for all populations including new-born infants. The devices are to be used by trained personnel only. The HearID system comes in two versions: HearID-b-wbMEPA, and HearID e-wbMEPA, where the difference is the variation of the hardware platform.	The Titan Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflexes. The Titan Impedance System measures various acoustic properties of the ear, namely power reflectance, power absorption, transmittance, reflectance group delay, complex acoustic impedance and admittance, and equivalent ear canal volume. These measures allow the evaluation of the functional condition of the middle and outer ear. The Titan Impedance System is suitable for all populations including new-born infants. The Titan Impedance 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 device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.	Same The first paragraph for Titan IMP440 WBT is identical with the previous version of the Titan with IMP440 Paragraph 2, 3 and 4 for Titan IMP440 WBT are identical with paragraph 2 for the predicate device. The 3rd paragraph for the predicate device is just a listing of variants of devices and has been omitted in the comparison
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 devices are to be used by trained personnel only.	The devices are to be used by trained personnel only.	Same
Safety standard	IEC 60601-1 (assumed)	IEC 60601-1	Same. It is assumed that the

	HearID (Predicate)	Titan IMP440 WBT	Comments
			predicate device complies as it at least is CE marked
EMC standard	IEC 60601-1-2 (assumed)	IEC 60601-1-2	Same. It is assumed that the predicate device complies as it at least is CE marked
Performance standard	Unknown	IEC 60645-5 / ANSI S3.39	The Titan IMP440 WBT complies with current state of the art standards. It is unknown if the predicate device complies.
Frequency Range	200-6000 Hz	250-8000Hz	Substantial equivalent Titan system use better transducers so the frequency range can be expanded to 8kHz. We trust that this does not influence the safety or effectiveness of the system
Intensity Range	0 – 80dB SPL	90/94 dB peSPL = 70/74 dB SPL	Substantial equivalent The intensity range is fixed but inside the range as the HeardID. The variable range for HeardID is used for pure tone stimulation and this is not relevant for the Titan WBT. We trust that when the range is inside the predicate device we can declare equivalence for safety and effectiveness.
Sample time	0.1 – 10 seconds per point		These parameters are not comparable, as the range for the predicate device is for pure tone, and the fixed sample time for Titan is fixed for the broadband click
		21, 5 Hz (Click sample time)	
Stimuli	Chirp	Chirp (Frequency linearized click)	Substantial equivalent
	Pure Tone	Not relevant	
Artefact rejection	Present	Present	Substantial equivalent. Titan IMP440 WBT has an artefact rejection system,

	HearID (Predicate)	Titan IMP440 WBT	Comments
			to remove responses contaminated with noise or noise artefacts. HearID has equivalent artefact rejection system to minimize noisy measurements.
Real time display of signal and noise	Present	No real time presentation.	Different. The Titan IMP440 WBT does not have real time display of signal and noise. Titan IMP440 WBT has a real time display of measurement data during acquisition. We trust that such "quality indicator" is irrelevant because the measurement time is so short that an indicator cannot be monitored with any benefit. After the test has finished, accepted and rejected sample ratio can be viewed.
Normative data	Present	Present	The functionality is substantial equivalent. Both systems have normative data present in the user interface to indicate normal middle ear function. Normative data are acquired individually for each system and is based on different databases. The Titan IMP440 WBT normative data is based on [1], [2]. The HearID norm data is based on other data.
Reflectance Area Index for enhanced diagnosis	Present	Present	Substantial equivalent. Titan IMP440 WBT uses a shaded area indicating normative region in either 10/90 percentiles or 5/95 percentiles for evaluating measurement results. Identical with normative data above
Customizable	Present	Present	Equivalent.

	HearID (Predicate)	Titan IMP440 WBT	Comments
measurement protocols.			Users can change the sequence of measurements to have test protocols fit for diagnostic and clinical purposes.
Customizable display parameters.	Present	Present	Substantial equivalent. The user can change how many and how graphs are presented on the display. Graphs may differ but the intended purpose is the same.
Otitis media with effusion examples	Present	Present	The functionality is substantial equivalent. For Titan IMP440 WBT these are sketched examples of curve characteristics based on measurements [4]
Measurements			
Power Reflectance	Present	Present	Substantial equivalent. Power Reflectance is equal to 1 - Power Absorbance. Power absorbance is plotted in Titan IMP440 WBT. Refer to Power Absorbance
Power Absorbance	Present	Present	Equivalent. Power Absorbance tells how much of the sound is absorbed by the middle ear, that value is identical to the Power Transmittance. The equivalency is based on result from [3]
Power Transmittance	Present	Present	Equivalent. Identical to Power Absorbance. Power absorbance is plotted in Titan IMP440 WBT. Refer to Power Absorbance
Acoustic Impedance	Present	Present	Equivalent. (ANSI S3.39 Quantities used for measurement of aural acoustic impedance and acoustic admittance) Acoustic Impedance is

	HearID (Predicate)	Titan IMP440 WBT	Comments
			calculated from the reflectance. Acoustic impedance calculated using Titan IMP440 WBT is similar to acoustics impedance calculated in single tone based Titan IMP440.
Acoustic Resistance	Present	Present	Equivalent. (ANSI S3.39 Quantities used for measurement of aural acoustic impedance and acoustic admittance) Acoustic Resistance is the real part of the complex valued Acoustic Impedance.
Acoustic Reactance	Present	Present	Equivalent. (ANSI S3.39 Quantities used for measurement of aural acoustic impedance and acoustic admittance) Acoustic Reactance is the imaginary part of the complex valued Acoustic Impedance.
Acoustic Admittance	Present	Present	Equivalent. (ANSI S3.39 Quantities used for measurement of aural acoustic impedance and acoustic admittance) Acoustic Admittance is the reciprocal of the Acoustic Impedance.
Acoustic Conductance	Present	Present	Equivalent. (ANSI S3.39 Quantities used for measurement of aural acoustic impedance and acoustic admittance) Acoustic Conductance is the real part of the complex valued Acoustic Admittance.
Acoustic Susceptance	Present	Present	Equivalent. (ANSI S3.39 Quantities used for measurement of aural acoustic impedance and acoustic admittance) Acoustic Susceptance is the imaginary part of the complex valued Acoustic Admittance.
Equivalent Volume	Present	Present	Equivalent. (ANSI S3.39

	HearID (Predicate)	Titan IMP440 WBT	Comments
			Clause 5.11) Equivalent volume is calculated from Acoustic Admittance and is proportional to with the following relation: $Equivalent\ Volume = \frac{f}{226} \cdot Acoustic\ Admittance$

[1]
Wideband absorbance tympanometry using pressure sweeps: System development and results on adults with normal hearing, Liu et al., J. Acoust. Soc. Am., Vol. 124, No. 6, page 3708-3719
[2]
Sound-Conduction Effects on Distortion-Product Otoacoustic Emission Screening Outcomes in Newborn Infants: Test Performance of Wideband Acoustic Transfer Functions and 1-kHz Tympanometry, Sandford et al., Ear & Hearing, vol. 30, no. 6, 635–652
[3]
Comparison of Wideband Energy Reflectance Obtained With Reflwin Interacoustics & Mimosa Acoustics Shahnaz, N., & Shaw. J. School of Audiology & Speech Sciences, University of British Columbia, Vancouver, BC, Canada
[4]
Acoustic Immittance Measures, Basic and Advanced Practice
Lisa Hunter, PhD, CCC-A, FAAA, Navid Shahnaz, PhD, Aud. (C)

Test summary

The Titan was tested according to current standards for IMP (impedance audiometry) and was found to conform to the standards. No clinical tests were performed, but based on the fulfillment of the international standards for IMP, and the comparison to predicate devices we trust the device is safe and effective.

Conclusion

We have compared the intended use and performance characteristics with the predicate devices. The Titan IMP440 WBT 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 IMP440 WBT was found to be substantially equivalent to the predicate devices in technological characteristics and indications for use.

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

November 29, 2012

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

Re: K121847
Trade/Device Name: Titan with IMP440 WBT
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory impedance tester
Regulatory Class: Class II
Product Code: ETY, GWJ
Dated: October 19, 2012
Received: October 22, 2012

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

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): K121847

Device Name: Titan, IMP440 WBT

Indications for Use:
The Titan Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflexes.

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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)

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

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K121847

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