K083861

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Titan

SUBMITTER INFORMATION

A	Company Name:	Interacoustics A/S
B	Company Address:	Drejervaenget 8 Assens, DK-5610, Denmark
C	Company Phone:	+45 6371 3555
	Company Fax:	+45 6371 3522
D	Contact Person:	Hanne Nielsen Quality Manager Interacoustics A/S
E	Date Summary Prepared:	04/11/2008

DEVICE IDENTIFICATION

A	Generic Device Name:	Tester, Auditory Impedance
B	Trade/proprietary Name:	Titan, Titan Shoulder Box, Titan Cradle, Titan Printer, Titan IMP440, Titan IMP440 Module, Titan Suite
C	Classification:	Class II
D	Product Code:	ETY

SUBSTANTIAL EQUIVALENCE

Predicate Device	Manufacture	510(k) No.	Date Cleared
AT235	Interacoustics	K994254	14/03/2000

DEVICE DESCRIPTION

Product name: Titan IMP440

Titan IMP440 consists of a handheld unit named Titan, Titan Cradle and PC software (Titan Suite and Titan IMP440 module). The measurements are controlled by the handheld unit. Titan IMP440 is going to be offered as 3 configurations that will support screening, diagnostic and clinic users. A license system makes it possible within each configuration to select which functionality the user wants to be incorporated in the system.

Titan IMP440 is an impedance product based on a hardware platform named Titan Platform. It uses a cabinet named Titan but may use any other cabinets as long as it meets the requirement of the platform. Other products will in the future be developed to the Titan platform and submitted as required and thereby become a part of the Titan System Family as Titan IMP440.

A connection box named Titan Shoulder Box enables different types of accessories to be connected to the hardware platform.

INTENDED 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 acoustics reflex.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Titan Impedance System and the predicate device has been performed. The results of this comparison demonstrate that the Titan Impedance System is equivalent to the marketed predicate device.

PERFORMANCE DATA

The performance data indicated that the Titan Impedance System meets all specified requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 09 2009

Interacoustics A/S
Ms. Hanne Nielsen
Quality manager
Drejervaenget 8
Assens, DK-5610. Denmark

Re: K083861
Trade/Device Name: Titan IMP440
Regulation Number: 21 CFR 874.1090
Regulatory Class: Class II
Product Code: ETY
Dated: March 5, 2009
Received: March 9, 2009

Dear Ms. Nielson:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

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

K083861

Indications for Use

510(k) Number (if known): K083861

Device Name: Interacoustics A/S Titan IMP440

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 acoustics reflex.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K083861