DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 15, 2015

Interacoustics A/S
c/o Mr. Eric Nielsen
Director, Regulatory & Compliance
Drejervaenget 8
5610 Assens
Denmark

Re: K151616
Trade/Device Name: AT235
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory Impedance Tester
Regulatory Class: Class II
Product Code: ETY
Dated: June 11, 2015
Received: June 15, 2015

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151616

Device Name
AT235

Indications for Use *(Describe)*

The Interacoustics AT235 Impedance Audiometer is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry, acoustic reflex and air conduction audiometry.

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

AT235

Submitter Information:

Company Name	Interacoustics A/S
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Contact Person	Erik Nielsen, Director, Regulatory & Compliance,
Date Summary Prepared	June 12, 2015

Device Identification:

Trade Name	AT235
Common Name	Audiometric equipment
Classification Name	Tester, Auditory Impedance
Product Code	ETY
Panel	Ear Nose & Throat
Device Class	Class II (According to 21 CFR 874.1090)

Predicate Devices:

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

Device Description	AT235 is an auditory impedance analyser. The device 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 device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of middle ear pathologies. The device is also used to measure the acoustic reflex threshold which occurs due to contractions of the stapedial muscle following exposure to a strong stimulus. This test allow to assess between central and peripheral pathologies and to identify where the patients uncomfortable loudness level may reside. The uncomfortable loudness level is useful when providing rehabilitative amplification methods and determining the correct management process for the patient. The AT235 also includes basic audiometry functions. The instrument is software controlled. The software controls the probe (tone and pressure) stimuli, measures the result and presents the result on a built in display. All functions are set and interpreted by the operator (There are no interpretations of results in the device). The technological characteristics are substantially equivalent with predicate device. All technological characteristics are in compliance with the consensus standard ANSI S3.39 for auditory impedance testers
Indications for Use	The Interacoustics AT235 Impedance Audiometer is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry, acoustic reflex and air conduction audiometry.
Intended operator	The AT235 tympanometer is intended to be used by an audiologist, hearing healthcare professional, or trained technician.
Technological Characteristics	The instrument is software controlled. The software controls the probe (tone and pressure) stimuli, measures the result and presents the result on a built in display. All functions are set and interpreted by the operator (There are no interpretations of results in the device). The technological characteristics are substantially equivalent with predicate device. All technological characteristics are in compliance with the consensus standard ANSI S3.39 for auditory impedance testers
Nonclinical tests summary	Following the design control procedure the design verification and validation were performed according to current standards for medical device safety and EMC and performance of impedance

	tester. The device was found in compliance with current standards and demonstrated substantial equivalence with the predicate device.
Clinical tests	None applicable
Conclusion	The AT235 as a modification to the predicate device (the previous cleared revision of AT235) uses the same or identical technology and has the same intended use as the predicate device. We trust that the verification and validation activities show substantial equivalence with the predicate device and that the modified AT235 is as safe and effective as the predicate device for its claimed purpose.