K994254

MAR 14 2000

510(k) SUMMARY

PREPARED BY:	INTERNATIONAL DISTRIBUTORS OF ELECTRONICS FOR MEDICINE, INC. (IDEM) 4814 East Second Street Benicia, CA 94510
CONTACT PERSON:	Donna Ward, President
TELEPHONE:	800-947-6334
DATE ON WHICH THE SUMMARY WAS PREPARED:	December 14,1999
NAME OF DEVICE:	Interacoustics AT235 Impedance Audiometer
COMMON NAME:	Impedence Audiometer
PREDICATE DEVICE:	Interacoustics Impedance Audiometer

DESCRIPTION OF DEVICE:

The Interacoustics AT235 Impedence 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.

Comparison of the Interacoustics Model AT235 Impedance Audiometer and The Interacoustics AT22t Automatic Impedance Audiometer.

Indication for use – Identical for both units.

Similarities and differences:

Interacoustics AT235 Impedance Audiometer	Interacoustics AT22t Automatic Impedance Audiometer
Display Description: Digital	Digital
Available Frequencies: 125 Hz, 250 Hz, 500 Hz, 1kHz, 2kHz, 3kHz, 4kHz, 6kHz, and 8kHz	250 Hz, 500 Hz, 1kHz, 2kHz, 3kHz, 4kHz, 6kHz, and 8kHz
Probe Tone Frequency: 226Hz ± 3%	Same
Probe Tone Intensity: 85dB SPL ± 3dB	Same
Pressure Range: +300 to –600daPa	+200 to –300daPa
Compliance Range: 0,1 to 5 ml	Same
Transducers: TDH39 Single Contralateral Earphone, Probe with Probe Tip	Same
Patient response unit: Handheld Push Button Switch	Same
Compatible Windows Software: IABase95 Database program, Printview for On-line PC Monitoring and Printing, IA-NOAH-IMP Module for Interfacing to NOAH	Same
Tests: Tympanometry, Acoustic Reflex and Air Conduction Audiometry	Same
Calibration: Impedance: ANSI S 3.39-1987, IEC 1027-1991 Audiometer: ISO/R 389-1991	Same
Power: 100-120 V or 220-240V	Same
Size and Weight: 14" x 10" x 4"; 6 lbs.	14" x 16" x 6"; 15.5 lbs.

SAFETY AND EFFECTIVENESS:

The Interacoustics AT235 Impedance Audiometer is in compliance with the following performance and safety standards:

Audiometer: ANSI 3.6- 1989
IEC 645-1-1992 Type 4
Impedance: ANSI 3.39-1987
IEC 1027-1991 Type 2
Safety: IEC 601-1-1988

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2000

Ms. Donna Ward
President
International Distributors of Electronics For Medicine, Inc.
(IDEM)
4814 East Second Street
Benicia, CA 94510

Re: K994254
Trade Name: Interacoustics AT235 Impedance Audiometer
Regulatory Class: II
CFR: 874.1090
Product Code: 77ETY
Dated: December 15, 1999
Received: December 17, 1999

Dear Ms. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994254

Device Name: Interacoustics Model AT235 Impedance Audiometer

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K994254