K983832

JAN 25 1999

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:	707-746-6334
DATE ON WHICH THE SUMMARY WAS PREPARED:	October 1, 1998
NAME IF DEVICE:	Interacoustics Model MT10 Handheld Impedance Audiometer
COMMON NAME:	Impedance Audiometer
PREDICATE DEVICE:	Grason Stadler GSI- 37 Auto Tymp

DESCRIPTION OF DEVICE: Our device, the Model MT10 Handheld Impedance Audiometer is an easy to use handheld diagnostic middle ear analyzer that is well suited for providing quick and reliable results in both diagnostic and screening settings. The tympanometry test features a user selectable extended pressure range that is capable of –600daPa. Four ipsilateral reflexes at different frequencies may be tested at each ear. Reflex testing operates either at a user defined fixed level or uses an automatic intensity search function. It assists in the diagnosis of possible otologic disorders.

Comparison of the Interacoustics Model MT10 Handheld Impedance Audiometer and the Grason Stadler GSI-37 Auto Tymp.

Indication for use – Identical for both units.

Similarities and differences:

Model MT10 Handheld Impedance Audiometer	Equivalent – Grason Stadler GSI-37 Auto Tymp
Display Description: Digital	Digital
Lightweight, handheld	Lightweight, handheld

Hardcopy printout provides objective documentation of otitis media and other middle ear disorders.	Hardcopy printout provides objective documentation of otitis media and other middle ear disorders.
Intensity: 10dBHL to 50dBHL	Not applicable
Pressure range: +300 -600daPa/sec.	+200 –400 daPa/sec.
Compliance range: .0 to 2.5 cc displayed; .0 to 5.0 cc numeric	.0 to 1.5cm^3 displayed
Tests: tympanometry, acoustic reflex and screening audiometry	Tympanometry
Compatible Windows Software: IaBase 95 database program; Printview for on-line PC monitoring and printing; NOAH hearing aid fitting software	None
Standards: meets or exceeds standards specified in IEC 1027-1995, ANSI 3.60 –1989, ANSI 3.60-1985, Safety IEC 601-1-1988	Meets ANSI S3.39 – 1987 for Type 4 Instrument and IEC 601-1-1988
Available frequencies: .5kHz, 1kHz, 2kHz, 3kHz & 4kHz	Not applicable
Probe tone: frequency: 226 Hz, +/-3%	226 Hz, +/-3%
Amplitude: 85dB SPL +/-3dB	85.5 dB SPL, +/-2.0 dB
Power: NiMH batteries or Standard AA NiCa batteries	NiCad batteries
Direction of Pressure Sweep: positive to negative	Positive to negative
Size and Weight: Probe: 4" x 10" x 5"; 1 lb.; printer/charger: 12" x 9" x 4"; 4 lbs. 11.6 oz.	Probe: 2.4" x 8.3" x 4.3"; 10.5 oz; printer/charger 9" x 7.6" x 4"; 3 lbs.
External Power Supply: (optional) 1.8 lbs (recharger power supply EPS11 power transformer-11 volts)	External Power Supply: (optional) 1.5 lbs. (recharger power supply –9 volts)

SAFETY AND EFFECTIVENESS:

The Interacoustics Model MT10 Handheld Impedance Audiometer is in compliance with the following performance and safety standards:

> Standards in IEC 1027-1995, ANSI 3.60-1989, ANSI 3.60-1985, Safety IEC 601-1-1988. Approved for Medical CE-marking by Danish Notified Body D.G.M. Identification No. 0543, Quality System Certificate DGM 016 (CE 0543)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

Donna Ward
President
International Distributors of Electronics for Medicine, Inc.
4814 East Second Street
Benicia, CA 94510

Re: K983832
Interacoustics Model MT10 Handheld
Impedance Audiometer
Dated: October 28, 1998
Received: October 30, 1998
Regulatory class: II
21 CFR 874.1090/Procode: 77 ETY

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983832

Device Name: INTERACOUSTICS MODEL MT10 HANDHELD IMPEDANCE AUDIOMETER

Indications For Use:

The Interacoustics MT10 Handheld Impedance Audiometer is an easy to use handheld diagnostic middle ear analyzer that is well suited for providing quick and reliable results in both diagnostic and screening settings. The tympanometry test features a user selectable extended pressure range that is capable of –600daPa. Four ipsilateral reflexes at different frequencies may be tested at each ear. Reflex testing operates either at a user defined fixed level or uses an automatic intensity search function. It assists in the diagnosis of possible otologic disorders.

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983832

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

(Optional Format 1-2-96)