

MAY 17 1999

K990652
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: February 23, 1999

NAME IF DEVICE: Interacoustics Model AZ26
Clinical Impedance Audiometer

COMMON NAME: Clinical Impedance Audiometer

PREDICATE DEVICE: Interacoustics Model Clinical
Impedance Audiometer AZ26

DESCRIPTION OF DEVICE:

Our device, the Model AZ26 Clinical 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.

Comparison of the Interacoustics Model AZ26 Clinical Impedance Audiometer and the Interacoustics Clinical Impedance Audiometer Model AZ26

Indication for use – Identical for both units.

Similarities and differences:

Interacoustics AZ26 Clinical Impedance Audiometer

Interacoustics Clinical Impedance Audiometer Model AZ26 (OLDER MODEL)

Display Description: Digital	Digital
Available Frequencies: 250 Hz, 500 Hz, 1kHz, 2kHz, 3kHz, 4kHz, 6kHz, and 8kHz	Same
Probe Tone Frequency: 226Hz ± 1%	Same
Probe Tone Intensity: 85dB SPL ± 1.5dB	Same
Harmonic Distortion: Less than 5%	Same
Pressure Range: -600 to +300 daPa	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	IaBase Database program only
Tests: Tympanometry (Manual or Automatic), Acoustic Reflex, Eustachian Tube Test (Williams and Toynbee), Air Conduction Audiometry, and Gelle Test	All except the Gelle Test and Toynbee Eustachian Tube Test
Calibration: Impedance: ANSI S 3.39-1987, IEC 1027-1991 Audiometer: ISO/R 389-1991	Same
Pressure Release: Pressure Release Function	None
Size and Weight: 19" x 16" x 6"; 21 lbs.	Same
Power: 100-120 V or 220-240V	Same
Opt. External Keyboard: yes	no

INTERNATIONAL DISTRIBUTORS OF ELECTRONICS FOR MEDICINE, INC.
4814 EAST SECOND STREET, BENICIA, CA 94510 USA

SAFETY AND EFFECTIVENESS:

The Interacoustics Model AZ26 Clinical Impedance Audiometer is in compliance with the following performance and safety standards:

Audiometer: ANSI S 3.6-1996
IEC 645-1-1992, Type 4
Impedance: ANSI S 3.39-1987
IEC 1027-1991, Type 1
Safety: IEC 601-1-1988



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

Ms. Donna Ward
President
IDEM
4814 East Second Street
Benicia, CA 94510

Re: K990652

Device: Interacoustics Model AZ26 Clinical Impedance Audiometer

Dated: February 23, 1999

Received: March 1, 1999

Classification Regulation: 77 ETY Auditory Impedance Tester, 21 CFR 874.1090
77 EWO Audiometer, 21 CFR 874.1050

Regulatory Class: II

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): K990652

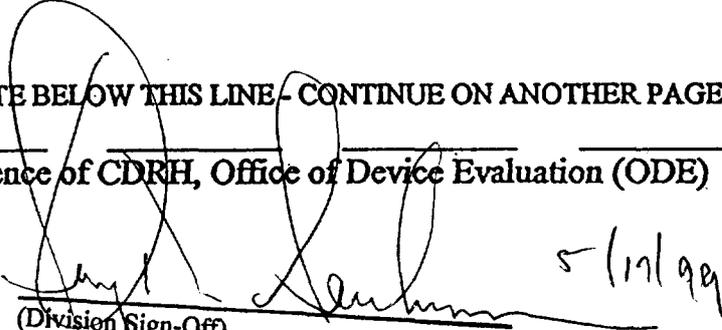
Interacoustics AZ26 Clinical Impedance Audiometer
Device Name: _____

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic Devices

5/17/99
510(k) Number K990652

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____