K981327

MAY 1 1 1998

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: 707-746-8597

DATE ON WHICH THE SUMMARY WAS PREPARED: March 25, 1998

NAME OF DEVICE: Interacoustics Diagnostic Audiometer Model AD226

COMMON NAME: Audiometer

PREDICATE DEVICE: Beltone Model 110 Audiometer

DESCRIPTION OF THE DEVICE

The interacoustics Model AD226 Diagnostic 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.

Comparison of the Interacoustics Model AD226 Acoustic audiometer and the Beltone Model 110 Audiometer follows:

Indication for use - Identical for both units.

Similarities and differences:

Model AD226 Audiometer	Beltone Model 110 Audiometer
Digital Display.	Analog and Digital Display.
Available Frequencies (Hz): 125, 250, 500, 750, 1000, 1500, 2000, 3000,	Identical.

4000, 6000, 8000	
Masking: Narrow Band Noise /White Noise.	Narrow Band Noise, Speech Weighted Noise, and White Noise.
Transducers: TDH 39 Headset; Ear-Tone 3A Insert Phones and B71 Bone Conductor.	TDH 50P Headset; B71 Bone Conductor.
Patient response unit: Hand held push-button switch.	Hand held push-button switch.
Compatible Windows Software: IaBase95 database program; PrintView for on-line PC Monitoring and printing; NOAH hearing aid fitting software. Connex hearing aid fitting software.	
Power: 100-115 or 230 V.	105-125 VAC, 50-60 Hz; : Optional : 208-250 VAC ,50-60 Hz.
Size and Weight; Audiometer alone: 12x9x4 inches. Weight 2.9 lbs. External Power supply: 1.8 lbs.	Audiometer alone: 16-1/8x9-3/4x 6-1/8 inches. Weight: 6lb 1oz.

SAFETY AND EFFECTIVENESS:

The Interacoustics Model AD226 Diagnostic Audiometer is in compliance with the following performance and safety standards:

Audiometers IEC 645-1 Type 3
ANSI 3.6-1989 and
Safety: EN 60601-1:1990
EMC: EN60601-1-2:1993

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 1 1 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981327
Interacoustics Diagnostic Audiometer Model AD226
Dated: April 9, 1998
Received: April 13, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
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): K981327

Device Name: Interacoustics Model AD226 Diagnostic Audiometer

Indications For Use:

The Interacoustics Model AD226 Diagnostic Audiometer is indicated for use in conducting diagnostic hearing evaluations and assisting 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 K981327

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

(Optional Format 1-2-96)