

AUG - 7 1998

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## 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: June 24, 1998

NAME OF DEVICE: Interacoustics Diagnostic Audiometer  
Model AD229

COMMON NAME: Audiometer

PREDICATE DEVICE: Qualitone Acoustic Appraiser CD-2  
Audiometer/Master Hearing Aid

## DESCRIPTION OF THE DEVICE:

The Interacoustics Model AD229 Diagnostic Audiometer is an electroacoustic device that produces controlled levels of test tones and signals. The unit employs digital readouts and includes an external power supply that contains an isolation transformer. The tones and sound signals are directed to the patient by means of the following transducers: TDH39 Audiometric Headset (standard); EAR-Tone 3A Insert Phones (optional); and B71 Bone Conductor (standard). This device also has master hearing aid capability and utilizes either the TDH39 Headset or the Ear-Tone 3A Insert Phones for the acoustical outputs.

**Comparison of the Interacoustics Model AD229 Diagnostic Audiometer and the Qualitone Acoustic Appraiser CD-2 Audiometer/ Master hearing aid follows:**

Indication for use - Identical for both units.

Similarities and differences:

Model AD229 Audiometer	Qualitone Acoustic Appraiser CD-2
Digital Display.	Analog and Digital Display.
Electronic Frequency Switching from 125 Hz to 8000 Hz with Digital Readout.	Identical.
Masking: Narrow Band Noise, Speech Weighted Noise, and White Noise.	Narrow Band Noise, Speech Weighted Noise, and White Noise Masking.
Transducers: TDH 39 Headset; Ear-Tone 3A Insert Phones and B71 Bone Conductor.	TDH 39 Headset; and Bone Oscillator Assembly.
Master Hearing Aid Capability -Yes	Yes
Speech and Tone Stimulation Capability - Yes	Yes
Patient response unit: Hand held push-button switch.	Hand held push-button switch.
Compatible Windows Software: laBase95 database program; PrintView for on-line PC Monitoring and printing; NOAH hearing aid fitting software. Connex hearing aid fitting software.	
Has output capability for optional external speakers.	Two external SK-3 speakers included.
Compatible with external CD or Tape Player.	Has built in CD Player.
Single Microphone.	Dual microphone.
Power: 100-115 or 230 V.	110 or 220VAC only, 50-60 Hz
Size and Weight; Audiometer alone: 14x10x4 inches. Weight 4 lbs.	Portable Case Dimensions: 18-1/2x14x9 inches. Weight: 27 lbs.
External Power supply: 1.8 lbs.	

#### SAFETY AND EFFECTIVENESS:

The Interacoustics Model AD229 Diagnostic Audiometer is in compliance with the following performance and safety standards:

Audiometers IEC 645-1-1991 Type 2  
ANSI 3.6- 1996 Type 2 and  
Safety: EN 60601-1:1990  
Electromagnetic Compatibility (EMC): EN 60601-1-2:1993



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Donna Ward  
President  
International Distributors of Electronics  
For Medicine, Inc.  
4814 East Second Street  
Benicia, CA 94510Re: K982249  
Interacoustics Model AD229 Diagnostic Audiometer  
Dated: June 24, 1998  
Received: June 26, 1998  
Regulatory class: II  
21 CFR 874.1050/Procode: 77 EWO  
21 CFR 874.3330/Procode: 77 KHL

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): \_\_\_\_\_

Device Name: Interacoustics Model AD229 Diagnostic Audiometer

Indications For Use:

The Interacoustics Model AD229 Diagnostic Audiometer is indicated for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

Because of its master hearing aid capability this device is also indicated for simulating a hearing aid during audiometric testing thus it may help in the selection and adjustment of a patient's hearing aid.

(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 982249

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_