



DEC 23 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Interacoustics AS
c/o Daniel Eggan
Interacoustics USA
7625 Golden Triangle Drive
Eden Prairie, MN 55344

Re: K052562

Trade/Device Name: Eclipse (Cabinet name), TEOAE25, EP15, EP25 or the combination
of Systems

Regulation Number: 21 CFR 874.1050

Regulation Name: Audiometer

Regulatory Class: Class II

Product Code: EWO, GWJ

Dated: November 29, 2005

Received: November 30, 2005

Dear Mr. Eggan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "David M. Whipple". The signature is written in a cursive, flowing style.

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Indications for Use

510(k) Number (if known):

Device Name: TEOAE25, EP15 or EP25, or the combination of systems

Indications For Use:

The Interacoustics EP systems, EP15 and EP25, are intended to assist in the evaluation, documentation and diagnosis of ear disorders on human beings. EP15/25 is a 2 channel ABR and the automatic recording of ABR waveforms makes it well suited for waveform based screening and the manual programmability options allow for comprehensive clinical use ranging from frequency specific threshold test to operating room applications and cochlear implant tests. The EP15 is a basic unit allowing only recording of the Auditory Brainstem Response (ABR), while the EP25 allows recording of the ABR and earlier and later potentials.

The Interacoustics TEOAE25 system is intended for determining Cochlear function using Transient Evoked Otoacoustic Emission click stimuli.

Both of these systems are of particular interest to Ear, Nose, and Throat doctors, Neurology specialties, Audiologist and other health professionals concerned with measuring auditory functions.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use *JMC*
(Per 21 CFR 801.109)

[Signature]

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K052562
Author Ejvind Christensen