DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 04 2007

Mimosa Acoustics, Inc.
c/o Patricia S. Jeng, Ph.D.
60 Hazelwood Drive, Suite #209
Champaign, IL 61820

Re: K063338
Trade/Device Name: HearID Transient-Evoked Otoacoustic Emission Analyzer (HearID+TE, T2001, and T2K)
Regulation Number: CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: October 31, 2006
Received: November 8, 2006

Dear Dr. Jeng:

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 forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063338

1 Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: HearID+TE Transient-Evoked Otoacoustic Emissions Analyzer

Indications for Use:

The intended use of the HearID+TE Transient-Evoked Otoacoustic Emissions Analyzer is to characterize inner-ear status and to assist in diagnosing inner-ear pathologies.

The HearID+TE system measures various acoustic properties of the inner ear, namely otoacoustic emission sound pressure level, signal-to-noise ratio, and reproducibility. These three properties may be measured within prescribed frequency bands or wideband. These measures allow for the evaluation of the functional condition of the inner ear, assuming a normal middle and outer ear. The HearID+TE system is suitable for all populations, including newborn infants. The HearID+TE system is to be used by trained personnel only.

The HearID system comes in two versions for use with different hardware platforms.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L. A. Chan, MD

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

510(k) Number K063338

Prescription Use X
(Per 21 CFR 801.109)