K981960

MAY 20 1998

510(k) Summary

PREPARED BY:	Mimosa Acoustics, Inc. 382 Forest Hill Way Mountainside, NJ 07092
CONTACT PERSON:	Patricia S. Jeng, President
TELEPHONE:	(908) 518 0711
DATE ON WHICH THE SUMMARY WAS PREPARED	April 22, 1998
NAME OF DEVICE:	CUB^{e}DIS II ^{TM} DPOAE Measurement System
COMMON NAME:	Otoacoustic Emissions Test Instrument
PREDICATE DEVICE:	Etymotic Research CUB^{e}DIS ^{TM} Oto-acoustic Emission
FUNCTION OF DEVICE:	The CUB^{e}DIS II ^{TM} DPOAE Measurement system is designed to provide acoustic stimuli for, and rapid clinical measurement and evaluation of, odd order distortion product tones generated by the cochlea and measured in the ear canal, at the audiometric frequencies (or other frequencies, as desired), between 500 through 8,000 Hz with no known artifacts, a low noise floor system, and a high signal-to-noise ratio.

SAFETY: The Mimosa Acoustic CUB^{e}DIS II ^{TM} DPOAE Measurement System is in compliance with the following standards:

EN 55011B Emissions Test
EN 60601-1-2 Immunity Test
IEC 801-2 Electrostatic Discharge Test
IEC 801-3 RF Electromagnetic Field Test
IEC 801-4 Fast Transients Test
IEC 801-5 Surge Test
Standard for Medical Electrical Equipment, Part 1:
General Requirements for Safety - UL 2601-1, Second Edition

Medical Electrical Equipment, Part 1:
General Requirements for Safety - CAN/CSA - C22.2 No. 601.1-M90.

COMPARISON of the Mimosa CUB^{e}DIS II ^{TM} device to the Etymtic Research CUB^{e}DIS ^{TM} unit:

INDICATION FOR USE: Identical for both products

Comaprision between Ariel_ DSP16+ and Mimosa DSP Boards

Comparisons between CUB^{e}DIS and CUB^{e}DIS II DPOAE Measurement Systems

	Computer Software Data Collection Graphic Displays Signal Processing	Computer Hardware DSP port	DSP Board	Probe Driver & Microphone Pre-Amplifier	Acoustic Probe & Ear-tips
CUB^{e}DIS	**Data Collections:** DOS in Fortran **Graphic displays** DOS Fortran Package **Signal Processing:** Fortran routines	Uses ISA full-size plug-in slot	Ariel_ DSP16 Plus	Etymotic Research ER-10C DPOAE Probe Driver-Preamp	Etymotic Research ER-10C DPOAE Low Noise Probe & ER10C14 series ear-tips
CUB^{e}DIS II	**Data Collections:** Window95 Visual C++ **Graphic displays** Window95 Visual C++ Window95 Visual Basic **Signal Processing:** Same routines as the Fortran routines in CUB^{e}DIS system.	Uses PCMCIA card plug-in slot	MA DSP PC Card (PCMCIA Card)	Mimosa Acoustics Probe Interface Cable (PIC) designed after ER-10C DPOAE Probe Driver-Preamp with Etymotic's help.	Same as above.

Comaprision between Ariel_ DSP16+ and Mimosa DSP Boards

Paramters	Ariel_ DSP16+	Mimosa DSP
Size (Type)	ISA full-size DSP board	PC (PCMCIA) Type II DSP card
INPUT		
Measurement Bandwidth	20 kHz	Same
ADC Resolution	16 bit	Same
ADC Differential Nonlinearity	–	±0.5 LSB
Instantaneous Dynamic Range - Line Inputs	88 dB	85 dB
Total Harmonic distortion - Line Inputs	0.025	0.006
Signal-to-Intermodulation distortion	–	90 dB (Typ)
Full Scale Input Voltage:	20 Vpp	2.9 Vpp
OUTPUT		
Measurement Bandwidth	20 kHz	Same
DAC Resolution	16 bits	Same
DAC Differential Nonlinearity	–	±0.5 LSB
Total Dynamic Range	88 dB	95 dB
Total Harmonic Distortion	0.025	0.01%
Signal-to-Intermodulation Distortion	–	85 dB
Full Scale Output Voltage	20 Vpp	2.8 Vpp

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Patricia S. Jeng
President
Mimosa Acoustics, Inc.
P.O. Box 1111
Mountainside, New Jersey 07092

Re: K981460
The CUB® DIS II ™ DPOAE
Measurement System
Dated: April 22, 1998
Received: April 23, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

Dear Ms. Jeng:

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): K981460

Device Name: The CUB^{e}DIS II™ DPOAE Measurement System

Indications For Use:

The intended use of The CUB^{e}DIS II™ DPOAE Measurement System is to determine the presence of cochlear function.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981460

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

(Optional Format 1-2-96)