K123624

MAR 2 8 2013

2 510(k) Summary

Date Prepared: November 20, 2012

Submitter: Mimosa Acoustics, Inc.
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Patricia S. Jeng, Ph.D.

Device Information:

Trade Name:	OtoStat DPOAE+MEPA, OtoStat MEPA, OtoStat DP, OtoStat DP2000
Common Name:	Distortion Product Otoacoustic Emission(DPOAE) and Wideband power reflectance (WBR), Wideband immittance
Classification:	OAE and Auditory Impedance Tester

Predicate Devices: CUB^{e}DIS-DPOAE Measurement System (K981460)
HearID Wideband Middle Ear Power Analyzer (MEPA) (K053216)

Device Description:

The OtoStat is a small portable handheld audiometric measurement device for measuring either DPOAE (distortion product otoacoustic emission), MEPA (middle ear power analysis), or both, where DPOAE is for evaluating cochlear function and MEPA for middle and outer ear status. Both MEPA and DPOAE measurements present acoustic stimulus into the ear canal via the loudspeakers in the acoustic ear probe, then record the complex pressure frequency responses via the microphone in the same acoustic ear probe. The responses are then analyzed and displayed against relevant normative data with recommended pass/refer indication for the trained user to determine the cochlear and middle ear status and for differential diagnosis.

Intended Use:

The intended use of the OtoStat DPOAE Measurement is to determine the presence of cochlear function.
The intended use of the OtoStat MEPA Middle Ear Power Analyzer is to characterize the middle ear status and to assist in diagnosing middle ear pathologies.
The intended use of the OtoStat DPOAE+MEPA is to determine the presence of cochlear and middle ear functions and to assist in differential diagnosis between cochlear and middle ear dysfunctions.
The device is suitable for all populations including new-born infants.
The device is to be used by trained personnel only.

Technical Characteristics:

Mimosa Acoustics OtoStat DPOAE and CUB^{e}DIS-DPOAE Measurement System (K981460) have the same technical design and use the same ear probe. The Oto-

Stat DPOAE is designed to provide stimuli for rapid clinical measurement and evaluation of odd order distortion product tones generated by the cochlea, and measured in the external ear canal. These tones are known as distortion-product otoacoustic emissions (DPOAEs). The system measures 4, 6, or 12 audiometric octave frequencies (or other frequencies, as desired), between 500 through 8000 Hz with no known artifacts, a low system-noise floor, and a high signal-to-noise ratio. The presence in the ear of a cubic $(2f1-f2)$ distortion tone that is detectable above the system noise level indicates the presence of healthy outer-hair-cell activity in the cochlea. The distortion product level and the corresponding noise floor level are plotted together with recommended pass/refer indicator.

Mimosa Acoustics OtoStat middle-ear power analyzer (MEPA) and HearID middle-ear power analyzer (MEPA3) (K053216) have the same technical design and use the same ear probe. With the ear probe in the patient's ear canal,the MEPA software generated acoustic stimulus is delivered into the external ear canal. Some of the sound is absorbed by the middle ear and the remainder is reflected back into the ear canal. The percentage of reflected power to incident power is defined as power reflectance $(|\Gamma|^2)$. Different middle-ear conditions affect the amount of power that is reflected or absorbed in each frequency band. MEPA measures and plots reflectance, as well as other related acoustic characteristics of the ear, over a wide frequency range, aiding the diagnosis of middle-ear disorders. The OtoStat MEPA instrumentation employs computer-generated stimuli, automated data monitoring, and advanced signal processing for noise and artifact rejection.

Nonclinical Performance Evaluations:

Following the design control procedure, the performance verification and validation of the OtoStat DPOAE and MEPA Measurement System was conducted by comparing their functionality against CUB^{e}DIS-DPOAE and HearID MEPA Measurement Systems, the predicate devices, for various test conditions. The test results demonstrate substantial equivalence in its effectiveness.

Bench mark evaluations were performed in accordance to the recognized consensus standards. The OtoStat has been demonstrated to comply with *Medical Electrical Equipment, Part 1: General Requirements for Safety (IEC 60601-1).*

Conclusion: The OtoStat DPOAE+MEPA as a modification to the predicate devices (the original devices) uses the same or identical technology and has the same intended use as the cited predicate devices, and is therefore substantially equivalent (21 CFR 807.92(a)(3)). The nonclinical performance evaluations have demonstrated it is as safe and effectiveness as the original and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2013

Mimosa Acoustics, Inc.
% Patricia S. Jeng, Ph.D.
335 N. Fremont Street
Champaign, IL 61820

Re: K123624
Trade/Device Name: OtoStat MEPA + DPOAE Measurement System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, ETY
Dated: February 25, 2013
Received: February 27, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann

for 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

1 Indications for Use Statement

Indications for Use

510(k) Number (if known): K123624

Device Name: OtoStat DPOAE + MEPA Measurement System

Indications for Use:

The intended use of the OtoStat DPOAE Measurement is to determine the presence of cochlear function.

The intended use of the OtoStat MEPA Middle Ear Power Analyzer is to characterize the middle ear status and to assist in diagnosing middle ear pathologies.

The intended use of the OtoStat DPOAE+MEPA is to determine the presence of cochlear and middle ear functions and to assist in differential diagnosis between cochlear and middle ear dysfunctions.

The OtoStat MEPA system measures various acoustic properties of the ear, namely power reflectance, power absorbance, transmittance, wideband immittance, and equivalent ear canal volume. These measures allow the evaluation of the functional condition of the middle and outer ear.

The device is suitable for all populations including new-born infants.

The device is to be used by trained personnel only.

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)

Shuchen Peng

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