K072033

Section 5: 510(k) Summary

Otodynamics LTD
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Phone: 44 1707-267667
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NOV 1 3 2007

Contact: John Morgan

Summary Prepared: April 25, 2007

Trade Name: *Otocheck*

Common Name:

Classification Name: Audiometer

Predicate Device Identification:

CFR21:
Product Code: EWO
Device Class:II
Legally Marketed Device: Otodynamics LTD ILO292DP Echoport & ILO2088 Echocheck
Manufacturer: Otodynamics LTD
K#: K983350 & K983352

Description:

The Otoport is a compact, self-contained, handheld Otoacoustic emission analyzer which has integral. rechargeable batteries for use.

The Otoport can screen for cochlear function using either Transient Evoked or Distortion Product Otacoustic Emissions (TE or DPOAEs). It uses state-of-the-art technology and high performance signal analysis to provide robust indications of cochlear function and high immunity to extraneous noise.

The Otoport has a high degree of connectivity, being capable of immediate connection to any IBM compatible PC via either USB port or Bluetooth wireless technology. The instrument will accept probes that are already in use with other products in the Otodynamics range of otoacoustic emission analyzer instruments. There is 100% compatibility between data recorded on the Otoport and data recorded on other Otodynamics OAE products.

Intended Use:

The Otoport can perform Transient Evoked (TE) and Distortion Product (DP) Oto-Acoustic Emission (OAE) measurements on ears via an ear piece or "probe" fitted into the ear canal.

Predicate Product Comparison Chart:

	Otodynamics ILO2088 Echocheck	Otodynamics ILO292 DP EchoportPlus	Otodynamics Otoport
510(k) Number	K983352	K983350	This 510(k)
Target population	Newborn, child, adult	Newborn, child, adult	Newborn, child, adult
Intended use	Transient Evoked otoacoustic screening technique	Distortion Product and Transient Evoked otoacoustic screening technique	Distortion Product and Transient Evoked otoacoustic screening technique
Physiological Measurement Technique employed	Non-invasive	Non-invasive	Non-invasive

Signal output:			
Frequency range: TEOAE DPOAE	1,500 to 3,200Hz N/A	500 to 6,000Hz 500 to 8,000Hz	500 to 6,000Hz 500 to 10,000Hz
Level range: TEOAE DPOAE	94 to 44dB SPL N/A	94 to 44dB SPL 35 to 75dB SPL	94 to 44dB SPL 35 to 75dB SPL
Level increments: TEOAE DPOAE	1.5dB steps +/-0.5 N/A	1.5dB steps +/-0.5 1dB steps +/-0.5	1dB steps +/-0.5 1dB steps +/-0.5
Signal to noise ratio	>85dB	>85dB	>85dB
Harmonic distortion: TEOAE DPOAE	N/A N/A	N/A <1%	N/A <1%
Intermodulation distortion	N/A	<-80dB	<-80dB
OAE Measurement system:			
Frequency range: TEOAE DPOAE	1,500 to 3,200Hz N/A	500 to 8,000Hz 500 to 10,000Hz	500 to 8,000Hz 500 to 10,000Hz
Amplitude range: TEOAE DPOAE	-10 to +94dB SPL N/A	-10 to +94dB SPL -20 to +80dB SPL	-10 to +94dB SPL -20 to +80dB SPL
Other parameters:			
External input voltage:	Via charger adaptor: 100v AC @ 60Hz for USA or 230v AC @ 50Hz	100v AC @ 60Hz for USA or 230v AC @ 50Hz	Via charger adaptor 100v AC @ 60Hz for USA or 230v AC @ 50Hz

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Internal power source:	2.4v rechargeable battery	7.5v rechargeable battery	3.6v rechargeable battery
Hard copy output:	Dedicated battery portable printer	Range of standard PC printers	Dedicated battery portable printer
Computer compatibility	PC Pentium III, 1 GHz, Windows 98 SE/ME/2000/XP, CD-ROM drive, RS232 communications port	Recommended minimum system: Laptop PC, VGA or better 486 33MHz 4MB RAM for DOS usage. Pentium laptop PC 8MB RAM for Windows 95 usage	PC Pentium III, 1 GHz, Windows 98 SE/ME/2000/XP, CD-ROM drive, USB port.
DPOAE Resolution:	N/A	1 point/octave to 8 points/octave	1 point/octave to 8 points/octave
TEOAE Resolution:	100Hz	100Hz	100Hz
Latency artefact check:	Yes	Yes	Yes
Real time data display:	No	Yes	Yes
Programmable test protocol	No	Yes	Yes
Fully self documented file structure:	Yes	Yes	Yes
Self-test:	Yes	Yes	Yes
Probe identity check:	No	Yes	Yes
Built-in keypad:	Yes (limited)	Yes	Yes
Built-in LCD screen display:	LEDs only	Yes	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Otodynamics Ltd.
c/o E. J. Smith
Smith Associates, Inc.
1676 Village Green, Suite A
Crofton, Maryland 21114

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Re: K072033
Trade/Device Name: Otodynamics Otoport
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: October 15, 2007
Received: October 15, 2007

Dear Mr. Smith:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

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Indications for Use

510(k) Number (if known): K072033

Device Name: *Otodynamics Otoport*

Indications for Use:

The Otoport can perform Transient Evoked (TE) and Distortion Product (DP) Oto-Acoustic Emission (OAE) measurements on ears via an ear piece or "probe" fitted into the ear canal.

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

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

510(k) Number K072033

Prescription Use X
(Per 21 CFR 801.109)