MAR 0 7 2007

510(k) Supplementary Information K070118

1. Submitters Name and Address: Tympany, Inc.
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3. Date Prepared: 26 January 2007

4. Device Name / Classification: Audiometer, Otoacoustic Emissions Analyzer (21 CFR 874.1050, Product Code EWO)
Auditory Impedance Tester, Tympanometer (21 CFR 874.1090, Product Codes ETY, NAS)

5. Proprietary / Trade Name: Otogram CA3350

6. Device Description:
The Otogram CA3350 is a computer-controlled, audiometric instrument combining the functions of an Audiometer, Distortion Product Otoacoustic Emissions Analyzer and Auditory Acoustic Impedance/Admittance Tester (i.e. Tympanometer). The device is controlled through the use of ASCII commands transmitted over a standard RS-232 communication port. Control software is installed on the supplied PC.

7. Intended Use:
The Otogram is an auditory diagnostic instrument intended to administer, under supervision by a trained healthcare professional, a battery of diagnostic and screening procedures that include the following:
1) Pure tone air and bone conduction audiometry with automated masking
2) Speech recognition threshold with automated masking
3) Speech discrimination with automated masking
4) Tympanometry
5) Acoustic reflex threshold, both ipsilateral and contralateral
6) Distortion product otoacoustic emissions
7) Pure tone Stenger
8) Patient survey

The Otogram is indicated for use by trained healthcare professionals on both adult and pediatric subjects for measurement of audiometric parameters to identify and supply data to help diagnose hearing loss and ear disorders.

8. Updated Substantial Equivalence Chart:

The previous version of this chart appears in Exhibits 5, 10, and 12.

Characteristic		**Predicate Impedance Audiometer Madsen Zodiac 901 K910247**	**Predicate Otoacoustic Emissions Bio-Logic AuDX K974076**	**Predicate Tympany Otogram Combined Device Impedance Audiometer Otoacoustic Emissions K041853**	**Tympany Otogram CA3350 Combined Device Impedance Audiometer Otoacoustic Emissions K070118**
Intended Use:		To diagnose a variety of middle ear disorders using impedance and static pressure measurements (i.e., tympanometry and acoustic reflex) in the ear canal.	To test cochlear function by measuring otoacoustic emissions.	To diagnose hearing and otologic disorders in the middle-ear and total ear system, using audiometry, Tympanometry, and acoustic reflex. To test cochlear function and presence of otoacoustic emissions.	To administer, under supervision by a trained healthcare professional, a battery of diagnostic and screening procedures that include pure tone air and bone conduction audiometry with automated masking, speech recognition threshold with automated masking, speech discrimination with automated masking, tympanometry, acoustic reflex threshold (both ipsilateral and contralateral), distortion product emissions, pure tone Stenger and patient survey.

Characteristic		Predicate Impedance Audiometer Madsen Zodiac 901 K910247	Predicate Otoacoustic Emissions Bio-Logic AuDX K974076	Predicate Tympany Otogram Combined Device Impedance Audiometer Otoacoustic Emissions K041853	Tympany Otogram CA3350 Combined Device Impedance Audiometer Otoacoustic Emissions K070118
Physical characteristics:					
	Computer interface:	RS 232C	RS 232C	Computer included, RS 232C	Computer included, RS 232C
	Internal printer	Thermal 112 mm, 4.5"	Thermal 59 mm, 2 1/4"	Thermal 58 mm, 2 1/4"	NA
	Printer interface	Parallel port	RS 232C thermal printer	Parallel port or USB	Parallel port or USB
	Display	Graphic supertwist LCD backlight, 256 lines x 128 dots	LCD 1" x 3"	Computer LCD 1024 x 768	Computer LCD 1024 x 768
		White text/graphics on blue background	Black and white	Color, resistive touchscreen	Color, resistive touchscreen
	Control interface	Keyboard	Touchpad	Keyboard, touchscreen	Keyboard, touchscreen
	Size/weight-metric	370 x 385 x 120 mm (W x D x H), 7.6 kg	98 x 41 x 197 mm (W x D x H), 0.45 kg	410 x 300 x 480 mm (W x D x H), 20.4 kg	356 x 348 x 493 mm (W x D x H), 21.1 kg
	Size/weight-American	14.8" x 15.4" x 4.8", 16.8 lbs	3 7/8" x 1 5/8" x 7 3/4", 1 lb	16" x 19", x 12", 45 lbs	14.0" x 13.7" x 19.4", 46.5 lbs
	Energy source	AC 50/60 Hz, 100-240 V	AC 50/60 Hz, 100-240 V	AC 50/60 Hz, 100-120 V	AC 47-63 Hz, 90-250 VAC
	Hardcopy output	Thermal paper or external printer paper	External thermal printer	Thermal paper or external printer paper	External printer paper
Standard and safety characteristics:					
	Performance and calibration	IEC 1027, ANSI S3.39	NA	IEC 1027, ANSI S3.39	IEC 1027, ANSI S3.39, IEC 60645-5
	Electrical safety	EN 60601-1, class I, type B	EN 55011: 1991 group 1 Class B	EN 60601-1, class I, type B	IEC 60601-1 and 60601-1-1, class I, type B and BF and IEC 60601-1-2 (EMC)

9. Significant changes from predicate Tympany Otogram combination device:

- Expansion of intended use to include use by "trained healthcare professional" vs. "qualified/trained audiologist"
    - The indications for use stated in the 501(k) submission for the Bio-Logic AuDX device (K974076) indicates use by a "trained health care professional (for example an Audiologist)"
    - Training for the Otogram CA3350 includes a thorough review and training using the User Instruction Guide included in Exhibit 13 of the 510(k) submission.
    - Comparison testing with predicate devices was performed by a Hearing Instrument Specialist Intern – someone who has been trained on the use of the equipment, but is not an audiologist. Test reports are contained in Exhibit 12 of the 510(k) submission.
- Different computer and improved design on various components and assemblies.
    - Computer specifications and design specifications are contained in Exhibit 11 of the 510(k) submission.

10. Safety and Effectiveness comparison to predicate devices:

The results of bench, user, and laboratory testing indicate that the new device is as safe and effective as the predicate devices.

11. Conclusion:

After analyzing both bench and user testing data, it is the conclusion of Tympany Inc. that the Tympany Otogram CA3350 is safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tympany, Inc.
c/o Lex J. Pearce
2795 East Cottonwood Parkway, Suite 660
Salt Lake City, UT 84121

Re: K070118
Trade/Device Name: Otogram CA3350
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, NAS, ETY
Dated: January 11, 2007
Received: January 12, 2007

Dear Mr. Pearce:

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

Indications for Use

510(k) Number (if known): K070118

Device Name: Otogram CA3350

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shu Chen Peng

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

510(k) Number K070118

Prescription Use ✓
(Per 21 CFR 801.109)