K041853

SEP - 3 2004

EXHIBIT 2

Tympany Inc.
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Contact: Kenneth Barrow, Vice President

Prepared July 2, 2004

510(k) Summary

1. **Identification of the Device:**
   Proprietary-Trade Name: Otogram
   Classification Name: Audiometer 77 EWO. (Otoacoustic emission devices are not exempt) and 77 ETY, Admittance Meter (874.1090
   Common/Usual Name: Audiometer, Impedance Audiometer, Otoacoustic Emissions Device

2. **Equivalent legally marketed devices** This product is similar in design and function to the Madsen Zodiac, K910247 and the Biologic Audx, K974076

3. **Indications for Use (intended use)** "Otogram" can perform the functions of:
   1. Pure tone and speech audiometer,
   2. Impedance audiometer (tympanometry, acoustic reflex), and
   3. Distortion product otoacoustic emissions analyzer.

   The unit is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement of acoustic impedance.

4. **Description of the Device:** The Otogram is a computer-controlled, audiometric instrument combining the functions of an Audiometer, a Impedance Instrument, and a DPOAE Instrument. 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. The device performs comprehensive audiometry; tympanometry, acoustic reflex; and otoacoustic emissions. Additional features include manual audiometer and NOAH v.3 compliant (hearing aid fitting software). Available in multiple languages, including English, Spanish, Russian, Mandarin, Vietnamese, and Korean.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, user, and laboratory testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Characteristic		Predicate Impedance Audiometer Madsen Zodiac 901 K910247	Predicate Otoacoustic Emissions Bio-Logic AuDX K974076	Tympany Otogram Combined Device Impedance Audiometer Otoacoustic Emissions
Intended Use:		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 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.
Technical characteristics				
Probe tone:				
	Probe tone frequency	226 Hz	NA	226 Hz, +/- 3%
	Probe tone level	85 dB SPL	NA	70 dB SPL, +/- 3 dB
Admittance measurement:				
	Total range	0.1 ml to 8.0 ml	NA	0.2 ml to 6.0 ml
	Reflex range	0 ul to 375 ul	NA	0 ul to 375 ul
	Calibration	2 cc cavity		0.5, 2, 5 cc cavity
Pressure system:				
	Pump system	Plunger type; stepper motor, digitally controlled	NA	Peristaltic pump; stepper motor, digitally controlled
	Pressure range - normal	+200 to -400 daPa	NA	+200 to -400 daPa
	Pressure range - extended	+400 to -600 daPa	NA	NA
	Accuracy	+/- 10% or +/- 10 daPa (whichever is greater)	NA	+/- 15% or +/- 10 daPa (whichever is greater)
	Pump speed	As fast as possible:	NA	50 daPa/sec to 150 daPa/sec
		400 daPa/sec, 200 daPa/sec, 100 daPa/sec, 50 daPa/sec	NA	
		Manuals speed control	NA	NA
	Air release	Mechanical safety release valve set to +600 and -800 daPa	NA	Mechanical safety release valve set to +600 and -600 daPa
		Manual & automatic air release	NA	Manual & automatic air release
Ipsi/contralateral stimuli				
	Pure tone	0.5, 1, 2, 4 kHz	NA	0.5, 1, 2, 4 kHz
	Step size	1, 2, 5, 10 dB	NA	1 to 10 dB
	Attenuator range, ipsi lateral stimulus	0.5, 1.0, 2.0, kHz 50-115 dB HL, 4.0 kHz 50-90 dB HL	NA	0.5, 1.0, 2.0, 4.0 kHz 80-105 dB HL
	Attenuator range, contra lateral stimulus	0.5, 1.0, 2.0, 4.0 kHz 50-100 dB HL, white noise	NA	0.5, 1.0, 2.0, 4.0 kHz 80-105 dB HL
	Frequency accuracy	+/- 0.5%	+/- .5%	+/- 0.5%
Distortion Product Otoacoustic Emissions				
	Stimulus	NA	2 pure tone stimulus	2 pure tone stimulus

Characteristic		Predicate Impedance Audiometer Madsen Zodiac 901 K910247	Predicate Otoacoustic Emissions Bio-Logic AuDX K974076	Tympany Otogram Combined Device Impedance Audiometer Otoacoustic Emissions
			channels	channels
	F2 test frequency	NA	2.0, 3.0, 4.0, 5.0 kHz	1.0, 1.5, 2.0, 3.0, 4.0 kHz
	Stimulus level range	NA	55 dB SPL and 65 dB SPL	45-70 dB SPL
Physical characteristics:				
	Computer interface	RS 232C	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"
	Printer interface	Parallel port	RS 232C thermal printer	Parallel port or USB
	Display	Graphic supertwist LCD backlight, 256 lines x 128 dots	LCD 1" x 3"	Computer LCD 1024 x 768
		White text/graphics on blue background	Black and white	Color, resistive touchscreen
	Control interface	Keyboard	Touchpad	Keyboard, touchscreen
	Size/weight - metric	370 x 385 x 120 mm (W x D x H), 7.6kg	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
	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 lbs	16" x 19" x 12", 45 lbs
	Energy source	AC 50/60 Hz, 100-240 V	AC 50/60 Hz, 100-240 V	AC 50/60 Hz, 100-120 V
	Hardcopy output	Thermal paper or external printer paper	External thermal printer	Thermal paper or external printer paper
Standard and safety characteristics				
	Performance and calibration	IEC 1027, ANSI S3.39	NA	IEC 1027, ANSI S3.39
	Electrical safety	EN 60601-1, class I, type B	EN 55011: 1991 Group 1 Class B	EN 60601-1, class I, type B

7. Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2004

Tympany, Inc.
c/o Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K041853
Trade/Device Name: Otogram, Audiometer, Impedance Audiometer, and Otoacoustics Emissions Device
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: ETY; ETW
Dated: July 6, 2004
Received: July 9, 2004

Dear Mr. Kamm:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, 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): K041853

Device Name: "Otogram" Combination –(Pure tone and speech audiometer, impedance audiometer, and distortion product otoacoustic emissions analyzer.)

Indications For Use:

"Otogram" can perform the functions of:
1. Pure tone and speech audiometer,
2. Impedance audiometer (tympanometry, acoustic reflex), and
3. Distortion product otoacoustic emissions analyzer.

The unit is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement of acoustic impedance.

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)

Prescription Use TYC 8/30/04
(Per 21 CFR 801.109)

TYC 8/30/04

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

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