Amplivox, Ltd.  
% Mr. Daniel Kamm  
Principal Engineer  
Kamm & Associates  
8870 Ravello Ct.  
Naples, FL  34114

Re:  K150163  
Trade/Device Name: Otowave 202 Portable Tympanometer  
Regulation Number: 21 CFR 874.1090  
Regulation Name: Auditory Impedance Tester  
Regulatory Class: Class II  
Product Code: NAS  
Dated: January 19, 2015  
Received: January 26, 2015

April 23, 2015

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. 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 and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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
Indications for Use

The Amplivox Otowave 202 is designed for use by trained operators (audiologists, general practitioners, hearing aid dispensers, and child health professionals) in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders in the general population associated with the functioning of the middle ear. The instrument performs two types of measurement: Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures. Reflex tests are used to measure stapedial reflexes. The Otowave measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.

Type of Use (Select one or both, as applicable)

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

“DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.”

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
1. **Identification of the Device:**
   - Proprietary-Trade Name: Otowave 202
   - Classification Name/Product Code: Auditory impedance tester. Code: NAS
   - Regulation: 874.1090 Auditory impedance tester
   - Common/Usual Name: Tympanometer

2. **Equivalent legally marketed devices:** Amplivox Otowave 102, K081841

3. **Description of the Device:** The Otowave 202 relies heavily on long-established practice in the clinical area of middle-ear measurements, and implements tympanometer functionality in a small desk-top device that may be powered from the mains (via a d.c. adapter) or by internal batteries. Stimuli are applied to the patient by means of a probe mounted on a flexible connecting lead for ease of use (especially with neonates) and additional contralateral stimuli are available if required via a separate plug-in transducer. Operation is via an intuitive menu-driven user interface, with test data displayed on the integral screen and capable of download to a PC via a USB connection and to a printer via an infrared communications (IrDA) interface.
   Tympanometers work by measuring the admittance of the tympanic membrane while the pressure in the ear canal is varied. The admittance is at a maximum when the air pressure across the tympanic membrane is balanced.

4. **Indications for Use:** The Amplivox Otowave 202 is designed for use by trained operators (audiologists, general practitioners, hearing aid dispensers, and child health professionals) in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders in the general population associated with the functioning of the middle ear. The instrument performs two types of measurement: Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures. Reflex tests are used to measure stapedial reflexes. The Otowave measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.

5. **Safety and Effectiveness, comparison to predicate device:** This device has the same indications for use as the predicate device K081841 and employs similar technology to accomplish the same tasks. A detailed comparison table is provided below.
### 6. Substantial Equivalence Chart

<table>
<thead>
<tr>
<th>Indications for Use:</th>
<th>Amplivox Otowave 102, K081841</th>
<th>Amplivox Otowave 202 K150163</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The Amplivox Otowave is designed for use by trained operators in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders associated with the functioning of the middle ear. The instrument performs two types of measurement: Tympanometry is used to measure the compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures. Reflex tests are used to measure stapedial reflexes. The Otowave measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.</td>
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</tr>
<tr>
<td><strong>Configuration</strong></td>
<td>Hand held battery operated</td>
<td>Hand held battery operated or AC line</td>
</tr>
<tr>
<td><strong>Photo</strong></td>
<td><img src="image1" alt="Amplivox Otowave 102" /></td>
<td><img src="image2" alt="Amplivox Otowave 202" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>TYMPANOMETRY MEASUREMENTS</strong></th>
<th>Amplivox Otowave 102, K081841</th>
<th>Amplivox Otowave 202 K150163</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probe tone: 226Hz +/- 2%, 85dB +/-2dB</td>
<td>Probe tone: 226Hz +/-2%; 85dB SPL +/-2dB</td>
<td></td>
</tr>
<tr>
<td>Pressure range: +200daPa to -400daPa +/-10daPa</td>
<td>Pressure range: +200daPa to -400daPa +/-10daPa or +/-10% (whichever is larger)</td>
<td></td>
</tr>
<tr>
<td>Direction of sweep: positive to negative</td>
<td>Direction of sweep: Positive to negative</td>
<td></td>
</tr>
<tr>
<td>Volumetric range: 0.2 to 5ml +/- 0.01ml or 10% over range whichever is greater</td>
<td>Volumetric range: 0.2ml to 5ml +/-0.1ml or +/-5% (whichever is larger)</td>
<td></td>
</tr>
<tr>
<td>Analysis performed: Compliance peak level, compliance peak pressure level, gradient and equivalent ear canal volume.</td>
<td>Analysis performed: Compliance peak level, compliance peak pressure level, gradient and equivalent ear canal volume</td>
<td></td>
</tr>
<tr>
<td><strong>Reflex Measurement</strong></td>
<td><strong>Amplivox Otowave 102, K081841</strong></td>
<td><strong>Amplivox Otowave 202 K150163</strong></td>
</tr>
<tr>
<td>------------------------</td>
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</tr>
<tr>
<td><strong>Otowave 102-1</strong></td>
<td>1KHz +/- 2%</td>
<td>Reflex type: Ipsilateral, contralateral or both</td>
</tr>
<tr>
<td><strong>Otowave 102-4</strong></td>
<td>500Hz, 1KHz, 2KHz &amp; 4KHz +/- 2%</td>
<td>Reflex frequencies: User defined – 500Hz, 1KHz, 2KHz and 4KHz (+/- 2%)</td>
</tr>
<tr>
<td><strong>Reflex dB range</strong></td>
<td>85 to 100 dBHL (programmable in 5 or 10 dB steps)</td>
<td>Reflex levels 70dBHL to 100dBHL +/-2dB (ipsilateral): (programmable in 5 or 10dB steps)</td>
</tr>
<tr>
<td><strong>Reflex measurement range</strong></td>
<td>0.01ml to 0.5ml +/- 0.01ml</td>
<td>Reflex levels 70dBHL to 110dBHL +/-2dB (contralateral): (programmable in 5 or 10dB steps)</td>
</tr>
<tr>
<td><strong>Analysis performed</strong></td>
<td>Reflex maximum amplitude and pass/fail at each test level.</td>
<td>Reflex detection 0.01ml to 0.5ml threshold: (configurable in 0.01ml steps) Analysis performed: Reflex maximum amplitude and pass/fail at each test level</td>
</tr>
</tbody>
</table>

**Printing**
- Designated printer: MCP8830 high speed portable thermal printer
- Data transfer: Infra-red IrDA 9600 Baud
- Printing may also be completed via a PC with the relevant applications

**Weight**
- (Including batteries): 380g
- 330g (without batteries); 430g (with batteries)
- Probe – 110g (incl. connecting cable)

**Size**
- 210 long x 80 wide x 40mm high envelope.
- 190 long x 85 wide x 40 high (excluding connections)
- Probe – 130 long x 25 (max) diameter

**Power/Battery**
- Battery specification: 4x Alkaline AA or 4x NiMH (>=2.3Ah) rechargeable
- Mains – Amplivox mains adapter (approved to medical safety standards)
- Batteries – 4xAlkaline AA or 4xNiMH (rechargeable >2.3Ah)

**Display**
- LCD
- LCD

**Data management**
- Internal database
- 30 patient records
- Patient record identification
- NOAH3 aud module
- Amplivox impedance module
- Data transfer: Infra-red IrDA 9600 Baud
- Internal database:
- 20 patient records with patient record identification
- Electronic data NOAH aud module storage (database Amplivox NOAH impedance module
- PC requirements: Transfer via USB cable/port

**Safety/EMC standards**
- Safety: EN60601-1: 1990
- EMC: EN 60601-1-2: 1993
- Safety: IEC 60601-1:2005 (see below)

**Impedance Standard**
- EN60645-5:2005 Type 2 tympanometer
- EN60645-5 Type 2 tympanometer

**7. Summary of non-clinical testing:** Material Evaluation to ISO 10993-1 was performed for the Otowave Tympanometer Ear-tips. (The material has not changed from our previous submission.) EMC testing was successfully performed according to EN 60601-1-2:2007. Safety testing was successfully performed according to IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) Medical electrical equipment – Part 1: General Requirements for Basic Safety and

Bench performance testing: Measurements were carried out with an Otowave 202 tympanometer to confirm that it satisfies the requirements of ANSI S3.39-1987/IEC60645. Software (i.e. firmware) validation: Performed per Amplivox 202 Tympanometer – Functional Specification / Test Plan. Risk analysis: Performed per Amplivox Otowave 202 Portable Tympanometer – Risk & Hazard Traceability Analysis plan.

8. **Summary of clinical testing:** Not applicable. Not required to establish substantial equivalence.

9. **Conclusion:** After analyzing bench testing, safety, EMC, and software validation (with risk analysis) testing we conclude that the Otowave 202 is as safe and effective as the predicate device, and has essentially the same technological characteristics, thus rendering it substantially equivalent to the predicate device.