DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 23, 2015

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150163

Device Name
Amplivox Otowave 202

Indications for Use *(Describe)*
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)*

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510(K) Summary, 510(k) K150163

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Date prepared: April 7, 2015

Prepared by: Chris Roerig, Engineering Manager

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

	Amplivox Otowave 102, K081841	Amplivox Otowave 202 K150163
Indications for Use:	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	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. (SAME)
Configuration	Hand held battery operated	Hand held battery operated or AC line
Photo		
TYMPANOMETRY MEASUREMENTS	Probe tone: 226Hz +/- 2%, 85dB +/-2dB Pressure range: +200daPa to -400daPa +/-10daPa Direction of sweep: positive to negative Volumetric range: 0.2 to 5ml +/- 0.01ml or 10% over range whichever is greater Analysis performed: Compliance peak level, compliance peak pressure level, gradient and equivalent ear canal volume.	Probe tone: 226Hz +/-2%; 85dB SPL +/-2dB Pressure range: +200daPa to -400daPa +/-10daPa or +/-10% (whichever is larger) Direction of sweep: Positive to negative Volumetric range: 0.2ml to 5ml +/-0.1ml or +/-5% (whichever is larger) Analysis performed: Compliance peal level, compliance peak pressure level, gradient and equivalent ear canal volume

	Amplivox Otowave 102, K081841	Amplivox Otowave 202 K150163
REFLEX MEASUREMENTS	Otowave 102-1: 1KHz +/ 2% Otowave 102-4: 500Hz, 1KHz, 2KHz & 4KHz +/- 2% Reflex dB range: 85 to 100 dBHL (programmable in 5 or 10 dB steps) Reflex measurement range: 0.01ml to 0.5ml +/- 0.01ml Analysis performed: Reflex maximum amplitude and pass/fail at each test level.	Reflex type: Ipsilateral, contralateral or both Reflex frequencies: User defi ned – 500Hz, 1kHz, 2kHz and 4kHz (+\- 2%) Refl ex levels 70dBHL to 100dBHL +/-2dB (ipsilateral): (programmable in 5 or 10dB steps) Reflex levels 70dBHL to 110dBHL +/-2dB (contralateral): (programmable in 5 or 10dB steps) 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
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	Two thermal printers (the Able AP1300 or Sanibel MPT-II) are available as options for use with the Otowave 202 both of which communicate via an infra-red link (IrDA).
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) EMC: EN 60601-1-2:2007
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

Essential Performance ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance, includes Deviations for United States CAN/CSA-C22.2 No. 60601-1 (2008) - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, includes National Differences for Canada, EN 60601-1: 2006 + CORR: 2010.
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.