510(K) SUMMARY

JAN 2 4 2014

1 - Information

510(k) Notification: **K133013**

GENERAL INFORMATION

Applicant: Inventis srl
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Date: December 18, 2013

DEVICE INFORMATION

The Inventis Middle Ear Analyzers (Flute and Viola) are conventional Auditory Impedance Testers. Below you can find the information related to the subject device.

Classification: 21 CFR§874.1090
Class II

Product Code: ETY

Trade Name: Middle Ear Analyzers, Flute and Viola

Common name Middle Ear Analyzer

Classification Name: Auditory Impedance Tester

PREDICATE DEVICES

Inventis Middle Ear Analyzers are substantially equivalent to the **Interacoustics Audio Traveller, Model AA222** for the constructive technological features and the performance.

INDICATIONS FOR USE

The Inventis Middle Ear Analyzers, Flute and Viola, are intended for use by trained operators in hospitals, nurseries, ENT clinics and audiology offices in conducting diagnostic hearing evaluations and assisting in diagnosis of possible otologic disorders. The Inventis Middle Ear Analyzers are intended for use on individuals six months of age or older. Flute is a tympanometer. Viola is a combination of audiometer and tympanometer.

PRODUCT DESCRIPTION

Flute is stand-alone tympanometry / reflex diagnostic device. Viola is a stand-alone combined unit, integrating a screening middle ear analyzer and a diagnostic audiometer capable of performing air and bone conduction threshold and speech exams. Flute and Viola are available with or without the integrated thermal printer.

2 - Substantial Equivalence

Inventis Middle Ear Analyzers (Flute and Viola) represent a modification of the cleared device, Interacoustics Audiotraveller, Model AA222 (510(k) number: K022728). The changes are of minor nature and do not concern the main functions of the predicate device. In particular, the differences regard:

- the pressure range, which is -600 to +400 daPa instead of -600 to +300 daPa and
- the introduction of an Internal Flash Memory where the speech material is stored.

In further support of a substantial equivalence determination, Section 12-*Substancial Equivalent Discussion* provides a comparison table between the submitted device and the predicate device.
The main comparison features are reported in the following table:

Features	Predicate Device	New Device	
	Interacoustics Audiotraveller, Model AA222 (510(k) n.: K022728)	**Flute**	**Viola**
Type	2 – Impedance (ANSI S3.39) 2 - Tone Audiometer (ANSI S3.6) B-E Speech Audiometer (ANSI S3.6)	2-Impedance (ANSI S3.39)	2-Impedance (ANSI S3.39) 3-Tone Audiometer (ANSI S3.6)
Probe Tone Frequency	226 Hz, 678 Hz, 800 Hz, 1 kHz	226 Hz, 1kHz (model HF)	226 Hz
Compliance Range	up to 8.0 ml	Same	
Pressure Range	-600 to +300 daPa	-600 to +400 daPa	
Safety Limitations for pressuring system	-800 daPa and +600 daPa	Same	
Acoustic Reflex outputs	Ipsi (I), Contra (C)	Same	
Acoustic Reflex Stimuli	250Hz (C), 500Hz, 1kHz, 2kHz, 3kHz, 4kHz, 6kHz (C), 8kHz (C), BBN, LPN, HPN	250Hz (C), 500Hz, 1kHz, 2kHz, 4kHz	
Audiometry: Available Frequencies	125Hz, 250Hz, 500Hz, 750Hz, 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz	-	Same
Audiometry Outputs	AC, BC, FF, insert mask	-	AC, BC, insert mask
Audiometry Inputs	PTA: pure tone, warble Speech: EXT1, EXT2, MIC Masking: NBN, WN, SN	-	PTA: pure tone, warble Speech: EXT1, EXT2, INT, MIC Masking: NBN, WN, SN
Max Power Consumption	45VA	19.2 W	
Display Description	Graphic monochrome display	Graphical color display	
Size	16.5 x 12.5 x 4 in (42 x 32 x 10.2 cm)	12.6 x 12.6 x 3.5 in (32 x 32 x 9 cm); w/printer: 12.6 x 15.4 x 3.5 in (32 x 39 x 9 cm)	
Weight	9 lbs (4,1 kg)	4.19 lbs (1,9 kg); w/printer: 5.29 lbs (2,4kg)	
Safety and Effectiveness	Impedance ANSI S3.39/IEC 60645-5: Type 2 Audiometer ANSI S3.6/IEC 60645-1: Type 2 Tone Audiometer ANSI S3.6/IEC 60645-2: Speech Type B-E Safety IEC 60601-1, Class I, Type B IEC 60601-1-2	Impedance ANSI S3.39/IEC 60645-5: Type 2 Audiometer (only Viola models) ANSI S3.6/IEC 60645-1: Type 3 Pure-tone Audiometer Safety IEC 60601-1, Class II, Type BF IEC 60601-1-2	

Inventis Middle Ear Analyzers (Flute and Viola) are substantially equivalent to the predicate device with regard to design, function, safety and technological and performance characteristic, intended use.

Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the proposed Inventis Middle Ear Analyzers are substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Inventis Middle Ear Analyzers (Flute and Viola) to support a determination of substantial equivalence to the predicate device. The safety and performance testing included the following tests:

- Electrical and mechanical safety testing
- Electromagnetic compatibility safety testing
- Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (ANSI S3.39)
- Instruments for the measurement of aural acoustic impedance (IEC 60645-5)

CONCLUSION STATEMENT

All the necessary electromagnetic compatibility and electrical safety tests were performed and documented in the Section 17-*Electromagnetic compatibility and electrical safety*. The results demonstrate that the Inventis Middle Ear Analyzer is in compliance with both the standards IEC 60601-1-2:2007 and IEC 60601-1:2005 and is safe as the predicate device.
All the necessary performance tests in support of substantial equivalence determination were conducted and documented in the Section 18-*Performance testing – Bench*. The tests demonstrate that the Inventis Middle Ear Analyzer is effective and performs as well as the predicate device.
The minor differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy.
Based on these results, we conclude that the Inventis Middle Ear Analyzer is substantially equivalent to the existing legally marketed device Interacoustics Audiotraveller Model AA222 under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 24, 2014

Inventis Srl
c/o Mr. Massimo Martinelli
General Manager
Corso Stati Uniti 1/3
35127, Padova
Italy

Re: K133013
Trade/Device Name: Inventis Middle Ear Analyzers, Flute and Viola
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory Impedance Tester
Regulatory Class: Class II
Product Code: ETY
Dated: December 18, 2013
Received: December 23, 2013

Dear Mr. Martinelli:

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); 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), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Enclosure

SECTION 04

INDICATIONS FOR USE STATEMENTS

INDICATIONS FOR USE

510(k) Number (if known): K133013

Device Name: Inventis Middle Ear Analyzers, Flute and Viola

Indications for Use: The Inventis Middle Ear Analyzers, Flute and Viola, are intended for use by trained operators in hospitals, nurseries, ENT clinics and audiology offices in conducting diagnostic hearing evaluations and assisting in diagnosis of possible otologic disorders. The Inventis Middle Ear Analyzers are intended for use on individuals six months of age or older. Flute is a tympanometer. Viola is a combination of audiometer and tympanometer, which reduces the amount of necessary equipment.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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