K983712

JAN 12 1999

EXHIBIT 2

Amplifon S.p.A.
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Contact: Giovanni Rollier, President

October 17, 1998

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: "Amplaid A311 Series™ "(AM 11, A311)
   Classification Name: Audiometer 77EWO
   Common/Usual Name: Clinical Audiometer

2. **Equivalent legally marketed devices** This product is similar in design and function to the Amplaid 309 Clinical Audiometer (K880059), Amplaid 308 Clinical Audiometer (K891988), and Amplaid A460 (K971747)

3. **Indications for Use (intended use)** The Amplaid A311 Series is a clinical diagnostic audiometer which can perform all audiometric tests normally performed in a clinical situation. It is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement and diagnosis of various types of hearing losses.

4. **Description of the Device:** The Amplaid A311 Series is a two channel clinical diagnostic audiometer which can perform all audiometric tests normally performed in a clinical situation. It provides testing capability for basic evaluation, cochlear versus retrocochlear dysfunction, central dysfunction and non-organic hearing loss. Other diagnostic audiometric tests are: pure tone, speech, Multifrequency, S.I.S.I., A.B.L.B. (Fowler), D.L.I. (Lüscher), M.L.B., and Tone Decay. The A311 Series comes in two models, both using the *same internal circuit board*: The AM11 which uses a personal computer as the user interface (communicates via RS232), and the A311, with uses a dedicated front panel keyboard with an LCD display.

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

6. Substantial Equivalence Chart

Characteristic	Predicate device: The Amplaid 309 K880059	New device: "Amplaid AM11™"	New device: "Amplaid A311™"
Intended Use:	Clinical diagnostic audiometric applications	(Same)	(Same)
Physical characteristics:			
Size/weight	17.3" W x 19.3" D x 7" H, 28 lbs.	12" W x 9.5" D x 2.75" H, 3 kg =6.6 lbs.	12.9" W x 15.7" D x 6.9" H, 6.8 kg =15 lbs
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz	(Same)	(Same)
User Interface	LCD/Dedicated Keyboard	Via attached personal computer	LCD/Dedicated Keyboard
Hardcopy Output:	Possible via computer interface	Via attached personal computer.	Via attached personal computer. (Future software release)
Standards and Safety characteristics:			
Audiometric:	ISO 389-1975, ANSI S3.6-1969, ANSI S3.13-1972, IEC 645	ISO 389-1989, ANSI S3.6-1989, IEC 60645	ISO 389-1989, ANSI S3.6-1989, IEC 60645
Electrical safety:	UL-544, IEC 601	UL 2601, IEC 60601-1	UL 2601, IEC 60601-1

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Amplifon S.p.A. that the "Amplaid A311 Series™" is as 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

JAN 12 1999

Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield, IL 60015

Re: K983712
Amplaid A311 Series Clinical Audiometers (AM11 and A311)
Dated: October 17, 1998
Received: October 21, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number [redacted]

Device Name: Amplaid A311 Series Clinical Audiometers (AM II & A311)

Indications for Use: The Amplaid A311 Series is a two channel clinical diagnostic audiometer which can perform all audiometric tests normally performed in a clinical situation. It is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement and diagnosis of various types of hearing losses.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983712

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)