K983915

JAN 29 1999

EXHIBIT 2

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

November 1, 1998

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: "Amplaid A315 and A319™"
   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 460 (K971747)

3. **Indications for Use (intended use)** The Amplaid A315 and A319 Series are clinical diagnostic audiometers 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 A315 and A319 are two channel clinical diagnostic audiometers which can perform all audiometric tests normally performed in a clinical situation. They provide testing capability for basic evaluation, cochlear versus retrocochlear dysfunction, central dysfunction and non-organic hearing loss. Other diagnostic audiometric tests are: pure tone, Speech, High Frequency, Multifrequency, Bekesy, S.I.S.I., A.B.L.B. (Fowler), D.L.I. (Lüscher), M.L.B., Tone Decay, and M.L.D.(Masking Level Difference).

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 460 (K971747)	New device: "Amplaid A315 and A319™"
Intended Use:	Clinical audiometric applications	(Same)
Physical characteristics:		
Size/weight	17.3" W x 19.3" D x 7" H, 28 lbs.	18.9" W x 15.7" D x 7.8" H, 8 kg =17.6 lbs.
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz	(Same)
Hardcopy Output:	Built in via 640 point thermal printer	External printer via parallel Centronics interface. Built in via 640 point thermal printer (Model A319), or via PC using ASA software.
Standards and Safety characteristics:		
Audiometric:	ISO 389-1989, ANSI S3.6-1989, IEC 645-1,-2, -4	(Same)
Electrical safety:	UL-544, IEC 601	UL-2601, IEC 60601

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Amplifon S.p.A. that the "Amplaid A315, A319 Series™" audiometers are as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering them 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 29 1999

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

Re: K983915
Amplaid A315 and A319 Audiometers
Dated: November 1, 1998
Received: November 4, 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 K98 K983915

Device Name: Amplaid A315, A319 Series Clinical Audiometers

Indications for Use: The Amplaid Models A315 and A319 are two channel clinical diagnostic audiometers 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)

David C. Dejoan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983915

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