K974235

EXHIBIT 2

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

FEB 10 1998

November 7, 1997

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: Amplaid AM50
   Classification Name: Auditory Impedance Tester 77ETY
   Common/Usual Name: Clinical Admittance Meter

2. **Equivalent legally marketed devices** This product is similar in design and function to the Amplaid 709 Admittance Meter (K802097) and the 770 Admittance Meter (K903066)

3. **Indications for Use (intended use)** The Amplaid AM50 is a Programmable Admittance Meter which can:
   - Evaluate middle ear functions such as otitis media, glue ear, eardrum scar tissues, perform myringotomy status, ossicular chain discontinuity ear canal volume, otosclerosis, stapes fixation.
   - Perform Acoustic reflex test.
   - Determine acoustic reflex threshold
   - Perform reflex decay test.

   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 AM50 ADMITTANCE METER performs plan and compensated tympanometry; Programmed and manual stimuli for ipsilateral and contralateral acoustic reflex; Automatic reflex threshold; and Decay measurements.

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 device. The same circuit technology is used in both devices. The only change is packaging and control software, whereby all keyboard, display, and control functions have been moved to the attached (via RS232) personal computer.

6. Substantial Equivalence Chart

Characteristic	Predicate device: Amplaid 770	New device: Amplaid AM50
Intended Use:	Clinical auditory impedance testing applications	(Same)
Technical characteristics	Per K903066	(Same)
Physical characteristics:		
Computer interface	RS232 Transmit only	RS232 Bi-directional
Display	Built-in liquid crystal	Via attached computer
Control interface	Built-in keyboard	Via attached computer or dedicated keyboard.
Size/weight	17.3" W x 19.3" D x 7" H, 28 lbs.	11.4" W x 12"D x 4" H 4.4 lbs.
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz	(Same)
Hardcopy Output:	Built-in Thermal printer	Via attached computer
Standards and Safety characteristics:		
Audiometric:	ANSI 1969, ISO 1975 for contralateral, 2 cm^3 cavity for ipsilateral, IEC 61027	(Same)
Electrical safety:	UL-544, IEC 601	(Same)

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Amplifon S.p.A. that the Amplaid AM50 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

FEB 10 1998

Amplifon S.p.A.
c/o Kamm & Associates
Daniel Kamm, P.E., Regulatory Engineer
P. O. Box 7007
Deerfield, Illinois 60015

Re: K974235
Amplaid AM50 Clinical Automatic
Programmable Admittance Meter
Dated: November 7, 1997
Received: November 12, 1997
Regulatory class: II
Procode: 77 ETY, 21 CFR 874.1090

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 to 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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

j) Indications for Use

510(k) Number K974235

Device Name: Amplaid AM50 Clinical Automatic Programmable Admittance Meter

Indications for Use: The Amplaid AM50 is a Programmable Admittance Meter which can

1. Evaluate middle ear functions such as otitis media, glue ear, eardrum scar tissues, perform myringotomy status, ossicular chain discontinuity ear canal volume, otosclerosis, stapes fixation.
2. Perform Acoustic reflex test.
3. Determine acoustic reflex threshold
4. Perform reflex decay test.

It is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement of acoustic impedance.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974235

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