SEP 20 1999

K992370

EXHIBIT 2

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

July 13, 1999

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: Amplaid A724 and A728
   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 770 Admittance Meter (K903066)

3. **Indications for Use (intended use)** The Amplaid A724 – A728 are Programmable Admittance Meters 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 A724 and A728 ADMITTANCE METERS perform plane 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.

6. Substantial Equivalence Chart

Characteristic	Predicate device: Amplaid 770 Per K903066	New device: Amplaid A724 –A728
Intended Use:	Clinical auditory impedance testing applications	(Same)
Technical characteristics		
Physical characteristics:		
Computer interface	RS232 Transmit only	RS232 Bi-directional
Display	Built-in liquid crystal	(Same)
Control interface	Built-in keyboard	(Same)
Size/weight	17.3" W x 19.3" D x 7" H, 28 lbs.	19.6"w x 16"d x 8"h 18.8 lbs.
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz	(Same)
Hardcopy Output:	Built-in Thermal printer	(Same)
Standards and Safety characteristics:		
Audiometric:	ANSI 3.6, 1969, ISO 1975 for contralateral, 2 cm^3 cavity for ipsilateral, IEC 61027	(Same or better) Standards updated and added: **IEC 61027 (1993);** Instruments for the measurement of aural acoustic impedance/admittance **ANSI S3.39(1987)**:Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance); **IEC 60645-1**: Audiometers - Part 1: Pure-tone audiometers **ANSI S3.6 (1996):** Specification for audiometers; **EN ISO 389 (1995):** Acoustics – Standard reference zero for the calibration of pure-tone air conduction audiometers
Electrical safety:	UL-544, IEC 601	Safety: EN 60601-1 Class I Type BF (1990); EN 60601-1/A1 (1993); EN 60601-1/A2 (1995); EN 60601-1/A13 (1996) EMC: EN 60601-1-2 (1993)

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Amplifon S.p.A. that the Amplaid A724 and A728 are 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

SEP 20 1999

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

Re: K992370
Trade Name: Amplaid A724 and A728 Clinical Automatic Programmable Admittance Meters
Regulatory Class: II
Product Code: 77 ETY
Dated: July 13, 1999
Received: July 15, 1999

Dear Mr. Kamm:

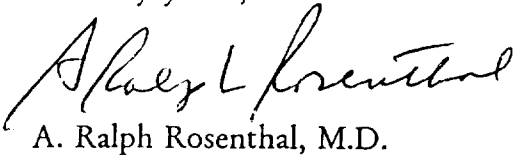
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K992370

Device Name: Amplaid A724 and A728 Clinical Automatic Programmable Admittance Meters

Indications for Use: The Amplaid A724 and A728 are Programmable Admittance Meters 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.

They ~~is~~ are 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)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)