K972959

FEB - 6 1998

EXHIBIT 2

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

August 8, 1997

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: Amplaid MK22
   Common/Usual Name: Evoked potential electrodiagnostic system
   Classification Names/ Device class: The electrodiagnostic system is a combination of devices which are Class II per regulations 882.1835, 882.1845, 882.1870, 882.1890, and 882.1900
   Classification Names/Product Codes: 84GWL(Signal Amplifier), 84GWK(signal conditioner), 84GWF(electrical stimulator), 84GWE(photic stimulator), 84GWJ(auditory stimulator).

2. **Equivalent legally marketed devices** This product is similar in design and function to the Amplaid USA, Inc. Evoked Potentials System MK15 (K861014)

3. **Indications for Use (intended uses)** Electronystagmography (for identification of middle ear conditions), Electroneurography (for facial nerve and blink reflex), Visual evoked potentials, Auditory evoked potentials, and Electrical (somatosensory) evoked potentials.

4. **Description of the Device:** The Amplaid MK22 Multi-channel system for electrodiagnosis consists of a two channel signal acquisition system coupled to a microcomputer which can perform signal averaging, storage and display, along with microcomputer controlled multiple mode evoked potential stimulators: auditory, visual, and electrical. A thermal printer is built in, and laser printer connection is supported.

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

6. Substantial Equivalence Chart

Characteristic	Predicate device: Amplaid MK15	New device: Amplaid MK22
Intended Uses:	Electronystagmography Electroneurography Visual evoked potentials, Auditory evoked potentials, Electrical (somatosensory) evoked potentials	(Same)
Physical characteristics:		
Number of channels	2 or 4	1 or 2
Size/weight	20.8" W x 18.9" D x 13.4 H, 44 lbs.	10" W x 14" D x 14" H 22.2 lbs
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz	95-250 VAC, 50-60 Hz 100 VA
Display	CRT monochrome (green), 9"	CRT, monochrome (green), 9" 640 x 400 (Same)
Hardcopy Output:	Built in via 640 point thermal printer or laser printer connection	(Same)
Standards and Safety characteristics:		
Electrical safety:	UL-544, IEC 601, Type BF	(Same)

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Amplifon S.p.A. that the Amplaid MK22 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

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Amplifon S.P.A.
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K972959
Trade Name: Amplaid MK22
Regulatory Class: II
Product Code: GWF
Dated: November 17, 1997
Received: November 18, 1997

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 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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K972959

Device Name: Amplaid MK22

Indications for Use: The Amplaid MK22 is a multi-channel system for electrodiagnosis capable of performing multisensory evoked potential tests including:

5. Electronystagmography
6. Visual evoked potentials,
7. Auditory evoked potentials, and
8. Electrical (somatosensory) evoked potentials.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972959

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