

MAR 16 1998

K971740

**EXHIBIT 2**

**Amplifon S.p.A.**  
**Via Ripamonti, 133**  
**20141 Milan, ITALY**  
**Tel ++39-2-57472.482**  
**Fax ++39-2-57409427**  
Contact: Giovanni Rollier, President

March 12, 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
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 use)** Electronystagmography (for identification of middle ear conditions), Visual evoked potentials, Auditory evoked potentials, and Electrical (somatosensory) evoked potentials.
4. **Description of the Device:** The Amplaid MK12 Multi-channel system for electrodiagnosis consists of a two or four 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 indicates that the new device is as safe and effective as the predicate devices.

## 6. Substantial Equivalence Chart

Characteristic	Predicate device: The Amplaid MK15	New device: "Amplaid MK12™"
Intended Use:	Electronystagmography, Visual Evoked Potentials, Auditory Evoked Potentials, Electrical (Somatosensory) Evoked Potentials	(Same)
Physical characteristics:		
Size/weight	20.8"W x 18.9"D x 13.4"H, 44 lbs.	21.25"H x 19.7"D x 7.9"H 28.6 lbs.
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz	(Same)
Hardcopy Output:	Possible via computer interface	Built in via 640 point thermal printer or laser printer connection
Standards and Safety characteristics:		
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 MK12™" 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Daniel Kamm  
c/o Kamm & Associates  
P.O. Box 7007  
Deerfield, Illinois 60015

MAR 16 1998

Re: K971740  
Trade Name: Amplaid MK12  
Regulatory Class: II  
Product Code: GWF  
Dated: March 2, 1998  
Received: March 4, 1998

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.

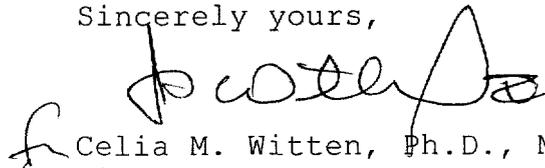
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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.

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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,



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**

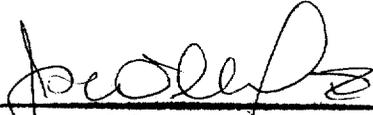
510(k) Number K971740

**Device Name:** Amplaid MK12

**Indications for Use:** The Amplaid MK12 is a multi-channel system for electrodiagnosis capable of performing multisensory evoked potential tests including:

1. Electronystagmography
2. Visual evoked potentials,
3. Auditory evoked potentials, and
4. Electrical (somatosensory) evoked potentials.

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of **General Restorative Devices**

510(k) Number \_\_\_\_\_

K971740

Prescription Use

OR

Over the Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)