K974658

Phonic Ear®
Innovative Communication Technologies

FEB 25 1998

510 (K) SUMMARY

of the

SAFETY AND EFFECTIVENESS OF THE DEVICE

510 (K) NOTIFICATION

INFRARED GROUP AMPLIFICATION SYSTEM

PHONIC EAR INC.

MODEL PE600 SERIES

Submitted by:

PHONIC EAR INCORPORATED
3880 Cypress Drive
Petaluma, CA 94954-7600

Establishment Registration No. 2918633

Telephone Number: (707) 769-1110
Fax Number: (707) 769-9624
Official Correspondent:: Robert L. Reinke, Ext. 298

December 1, 1997

510(k) NOTIFICATION
Phonic Ear Model PE600 Series Infrared Group Amplification System
December 1, 1997

SUMMARY OF THE SAFETY OF THE SYSTEM

1. The safety of this Infrared Amplification System is equivalent to approved systems of the same type.

2. While moderate sound pressure levels are produced by the PE600 Series receivers, this output can be limited to the output required by the user. Limiting can be accomplished by the setting of the volume controls in accordance with the tests made by a clinician, audiologist or hearing professional prior to use by the hearing impaired user.

3. Instructions for the user to follow, should the system not function as expected, are contained in the user information.

4. Complete technical specifications are contained in the user information.

5. The systems are distributed directly to qualified dispensers or others who are trained in the proper fitting and use of the system.

6. The system elements are housed in cases made of cycolac plastic which has few known side effects caused by the material.

7. A complete line of accessories to be used with the system elements are available from the manufacturer and a list of these accessories and a description of their use is contained in the user information.

8. Addresses and telephone numbers of authorized service centers are available to the user should any questions arise about the function of the system.

9. Detailed descriptions on the use, maintenance, adjustment and function of each element of the system are contained in the user information.

10. The system elements are powered by low voltage batteries which are contained within battery compartments that are fitted with tight snap fitting covers to prevent inadvertent opening. The battery circuits are protected by fusing devices to prevent over heating should a short circuit occur.

11. The user worn receivers are fitted with removable covers over the earphones that contact the skin and ears of the users, which can be removed for cleaning or exchange to prevent the spread or transmission of possible contamination.

510(k) NOTIFICATION
Phonic Ear Model PE600 Series Infrared Group Amplification System
December 1, 1997 Page 1

SUMMARY OF THE EFFECTIVENESS OF THE SYSTEM

1. The effectiveness of this Infrared Amplification System is equivalent to approved systems of the same type.

2. The infrared light gathering lenses on the receivers are designed to detect the sound signals from any angle providing for clear reception at any location within the installation.

3. The use of solid state surface mount components and integrated circuits allow the size and weight of the system elements to be reduced without the loss of any of the beneficial features provided in the design. Units are less obtrusive to the user because of the smaller size and easier to use because of the reduction in weight.

4. The use of several optional listening accessories provide a more natural sound to the user in different environments because the sounds are processed more like the sounds received by normal hearing persons.

5. The ability of the system elements to utilize a variety of listening accessories allow the user a wider choice of fitting possibilities to better meet their personal needs.

6. The inclusion of a battery charging LED indicator on the PE600R receiver insures that the device's rechargeable batteries will receive a full charge by confirming to the user that a positive charging connection has been made.

7. The ability of the receivers to operate on either rechargeable or throw-away batteries allow the user to select the power source most beneficial to their use.

8. The provision of optional receiver types provide the user with a selection which will best suit their own needs.

9. The combining of the power and amplifier circuits with the infrared LED circuits into one unit , provide easier installation and adjustment of the infrared emitter PE600E.

10. The ability of the PE600E to operate on both 2.3 Mhz and 2.8 Mhz simultaneously provides greater flexibility for the use of the system. Either stereo or 2-channel programs can be transmitted by the same system.

11. The use of the higher 2.3 Mhz and 2.8 Mhz transmission frequencies eliminates the interference which may be caused by electrical circuits and lighting, thus providing a clearer, interference free sound to the listener.

12. The ability of the PE600E Infrared Emitter to be mounted in several ways provide more flexibility for use as either a small portable system or in permanently installed systems for large auditoriums.

13. The ability of the systems to be enlarged by the addition of more infrared emitters provides full sound coverage even in very large installations.

14. The ability of the infrared receivers to power the tele-coil found in most hearing aids enables the users to utilize their own hearing aids which provide more convenience of use as well as allowing the user to hear the same sounds they would normally hear using only their hearing aid.

15. The design of the infrared detecting elements in the receivers allow the user to sit anywhere within the infrared environment without experiencing the dead spots or sound fade-outs usually found in most installations.

16. The use of an Infrared Group Amplification System provides increased speech understanding and word discrimination for the hearing impaired in listening environments such as school classrooms, concert halls, theaters or other similar situations where noises, reverberation or poor acoustical treatment may be found. The use of these systems also reduce the detrimental effects caused by the distance between the speaker or sound source and the hearing impaired listener. (See note.)

17. The ability of the infrared system to operate on two channels simultaneously allows the system to be used for language translation thus integrating users of different languages into the same environment.

18. The PE600 Infrared Systems are especially adaptable for use in installations where security of the sound is desired , such as in court rooms or jury deliberation rooms.

NOTE: *Effectiveness claims outlined in paragraph 16 have been substantiated by the results of many clinical studies made over the years since the introduction of FM Auditory Training Systems. Three such study reports by Dr. David Hawkins, Dr. Mark Ross, Robert Benoit, M.A. and Dr. Thomas Giolas form a part of this 510(k) submission.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1998

Robert L. Reinke
Phonic Ear, Inc.
3880 Cypress Drive
Petaluma, CA 94954-7600

Re: K974658
Phonic Ear Model: PE600E Infrared Emitter,
PE600R Infrared Receiver, PE601R Infrared Headset Receiver
and PE602R Infrared Headset Receiver
Dated: December 1, 1997
Received: December 15, 1997
Regulatory class: II
21 CFR 874.3320/Procode: 77 EPF

Dear Mr. Reinke:

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.

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

Enclosure

December 1, 1997

INDICATIONS FOR USE

510(k) Number: K974658

Device Name: INFRARED GROUP AMPLIFICATION SYSTEM - MODELS PE 600 SERIES

Indications For Use:

The Model PE 600 Series devices form the Impaired Group Amplification System which is used by adults and children in public halls, theaters, churches, courtrooms and other public gatherings and provide auditory assistance to hearing impaired persons.

1. The Model PE 600E is a power amplifier which is combined with an infrared LED array. Audio signals from a sound system are processed and broadcast into the listening area by means of infrared light.

2. The Model PE 600R is a body worn infrared receiver. It receives the infrared light signals from the PE 600E and converts these signals to high level audio signals required by the hearing impaired listener. The audio signals can be adjusted to meet the needs of the user.

3. The PE 601R is an Infrared Headset Receiver. It receives the infrared light signals from the PE 600E and converts these signals to audio signals required by the hearing impaired listener. This devise is capable of stereo reception so that different audio signals can be received simultaneously and fed to each ear separately.

4. The PE 602R is an Infrared Headset Receiver. It receives the infrared light signals from the PE 600E and converts these signals to audio signals required by the hearing impaired listener. The device is capable of receiving infrared light signals transmitted on two separate frequencies. A switch on the headset allows the user to select the program frequency desired. The selected program is heard in each ear.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____
(Optional Format 1-2-96)

Restricted Device
Per 874.420 and 421

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974658