K974287

FEB 10 1998

510 K NOTIFICATION

GROUP AUDITORY TRAINER
(Group Amplification System)

PHONIC EAR INC.

MODEL PE571R

Submitted by:

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

Establishment Registration No. 2918633

SUMMARY

of the

SAFETY AND EFFECTIVENESS OF THE DEVICE

510K NOTIFICATION
PHONIC EAR Model PE571R FM Receiver
November 7, 1997

SUMMARY OF THE SAFETY OF THE DEVICE

1. The safety of this auditory trainer FM receiver is equivalent to approved devices and systems of the same type.

2. While the highest sound pressure level produced by the device is above 132dBSPL, this output can be limited to the output required by the user. Limiting can be accomplished with a control set and locked by a clinician, audiologist or hearing professional prior to use by the hearing impaired person.

3. A notice of the devices' high output capability and a warning that high sound pressure could damage hearing are contained in the user information.

4. The audiological controls of the device can be set by a clinician, audiologist, or hearing professional prior to use by the hearing impaired person. These settings provide the proper amplification to match the hearing loss of the user and to preset the receivers for proper function with the accessories to be used.

5. The fitter controls are covered to prevent access by the user and can be adjusted only by use of special tools available to the hearing professional making the initial or subsequent adjustments.

6. Other safety notices as required by FDA rules are contained in the user information.

7. Device Maintenance and Care instructions are contained in the user information.

8. Instructions for the user to follow should the device not function as expected are contained in the user information.

SUMMARY OF THE SAFETY OF THE DEVICE

9. Complete technical specifications required by the FDA rules are contained in the user information. These specifications were obtained by testing devices per ANSI Standard ANSI.S3.22-1987 Specification of Hearing Aid Characteristics.

10. Devices are distributed directly to qualified schools or institutions or to Hearing Aid Dispensers, Audiologists, Clinics or others who are qualified to fit the devices to the hearing requirements of the user.

11. The device is powered by low voltage batteries which are contained within a battery compartment that is fitted with a locking cover to prevent inadvertent opening. The battery circuit is fused to prevent over heating should a short circuit occur.

12. The devices' plastic housing is made of Cycolac plastic which has few known side effects caused by the material. A warning to consult a physician should any affect to the skin be noticed, is contained in the user information.

13. A complete line of accessories to be used with the device are available from the manufacturer and a list of these accessories is contained in the user information.

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

15. Complete and detailed descriptions on the use, adjustments and functions of the device are contained in the user information.

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PHONIC EAR Model PE571R FM Receiver
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SUMMARY OF THE EFFECTIVENESS OF THE DEVICE

1. The maximum power output of the receiver can be set to the appropriate level required by the user and then locked at that level to prevent over amplification which could cause pain or discomfort to the listener.

2. The sound pressure level of the built-in receiver microphones and the level of the signal received from the FM transmitter can be independently controlled so that the proper balance between the two signal sources can be achieved.

3. The CHG/LOW BATT LED located on the front face of the receiver provides a positive indication that the unit's rechargeable batteries are receiving a charge and that the charging circuit is functioning properly. It also indicates when the unit's batteries are low and should be recharged or replaced.

4. The NO FM LED located on the front face of the receiver indicates when no FM signal is being received by a receiver..

5. The enlarging lens on the front face of the receiver enables the user to easily see the FM frequency channel number selected. Receivers and transmitters must be set to the same frequency channel in order to function together as a system.

6. The inclusion of a 3 position switch allows the receiver to be set to the various operating modes required by the user.

7. The inclusion of a 7 position FM level switch for each ear enables the receivers's audio signals to be attenuated so that the transmitter signals are emphasized over the environmental sounds picked up by the receiver's microphones.

8. The inclusion of a 7 position SSPL switch for each ear enables the output of the receiver to be limited to the sound pressure level best suited for the user.

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SUMMARY OF THE EFFECTIVENESS OF THE DEVICE

9. The inclusion of a 7 position GAIN switch for each ear enables the level of amplification to be set to best suit the users' needs.

10. The inclusion of a 7 position TONE switch for each ear enables the frequency response of the receiver to be set to best accommodate the specific hearing loss of the user.

11. The inclusion of a 2 position microphone switch which enables the receiver to be set for sound reception through the 2 built in environmental microphones or through the microphone contained in a behind-the-ear (BTE) device connected to the receiver.

12. The use of solid state surface mount components and integrated circuits allows the size and weight of the devices to be reduced without loss of any of the beneficial features provided in the design. It also allows the unit to be less obtrusive to the user because of smaller size and easier to use because of the reduction in weight.

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

14. The ability of this device to use a variety of listening accessories allows the user a wider choice of fitting possibilities to better meet their personal needs.

15. By selecting the mode of operation, FM signal only, FM signal and microphone signal together or microphone signal only, the user will be able to set the unit for optimum performance in most listening environments.

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SUMMARY OF THE EFFECTIVENESS OF THE DEVICE

16. The receiver's FM receiving frequency is controlled by 2 rotary switches accessible under a latching cover. This will enable the FM channels to be easily changed by the user as needed in various classroom environments or in other listening situations where multiple FM frequencies may be present.

17. The use of an FM Auditory Trainer (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 FM Systems also reduce the detrimental effects caused by the distance between the speaker or sound source and the hearing impaired listener.

Note: Effectiveness claims outlined in paragraph 17 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 510K submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1998

Robert L. Reinke
Director, Regulatory Affairs
Phonic Ear, Inc.
3880 Cypress Drive
Petaluma, California 94954-7600

Re: K974287
Group Auditory Trainer
(Group Amplification System)
Model PE571R
Dated: November 7, 1997
Received: November 14, 1997
Regulatory class: II
Procode: 77EPF, 21 CFR 874.3320

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 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

510(k) Number (if known): K974287

Device Name: P.E. 571R

Indications For Use:

This device is a receiver for an FM group auditory trainer. It is intended to be used with the Phonic Ear PE 571t group auditory trainer transmitter. Auditory trainers are used primarily in institutions (schools, churches, theaters, etc.) to allow teachers, ministers, etc. to communicate with individuals with hearing deficits.

This device can also be used with its built-in microphones or plug-in microphones as a stand alone assistive listening device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974287

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Restricted Device
Per 874.420 and 421