K043090

DEC 23 2004

510(k) Summary

Phonic Ear, Inc.
3880 Cypress Drive
Petaluma, California 94954-7600

Establishment Registration No. 2918633

Mr. Michael Gibbs
Telephone Number: (707)769-1110 Ext. 247
Fax Number: (707) 769-9624

Device Trade or Proprietary Names:	**EasyListener 2 FM Sound Field System** **Radium FM Sound Field System** **Vocalight Infrared Sound Field System**
Device Common Name:	Sound Field Amplification Systems
Classification Name:	Group Hearing Aid or Group Auditory Trainer
Device Classification:	Class II
Regulation Number:	874.3320
Product Code:	EPF

Intended Use of the Device:
Sound Field wireless amplification systems are intended for use as group auditory trainers used to communicate simultaneously with one or more listeners with normal hearing or hearing impairments. The device is used with an associated transmitter microphone and speaker systems and does not provide coupling to the ear through either earphones or earmolds.

These systems use FM and/or infrared wireless technology which include receivers, transmitters, and strategic placement of high quality speaker systems and can be used with or without BTE hearing aids and/or personal FM devices. The talker's voice is mildly amplified and dispersed throughout the room to assist listeners, regardless of seating location, to consistently hear what the talker is saying.

Identification of predicate devices:
Sound Field systems are substantially equivalent to various types of approved Group Hearing-Aids or Group Auditory Trainers that are directly connected or coupled to the listener as described above with similar results:

K974287 – FM Receiver Group Auditory Trainer-Solaris Binaural Hearing System

Description of the candidate devices:
Sound Field group amplification systems consist of FM or IR transmitters and microphone used by a speaker/instructor to send auditory signals to FM or IR receiver/amplifier which processes the voice signals and broadcast the signals through one or more loudspeakers. These systems are generally installed under the guidance of an audiologist or a sound contractor. Sound Field systems consist of an on/off switch and volume controls. Specifications and user guides are provided for Sound Field installation and use.

Sound Field systems are assembled from standard electronic components widely used by Group Hearing Aid and Group Auditory Trainer manufacturers. Sound Field wireless amplification systems amplify and broadcast the speaker/instructor's voice through strategically-mounted wall and/or ceiling loud speakers placed throughout the listening area to distribute the final processed signal (sound) of the speaker/instructor and are not directly connected or coupled to the listener.

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There are no known contraindications associated with the use of Sound Field group amplification systems. Many case studies, experiments, and trials exist that document the benefits and effectiveness of speech perception from Sound Field amplification.

Field studies were conducted in accordance with ANSI S12.60 Acoustical Performance Criteria, Design Requirements, and Guidelines for Schools. Prior to the issuance of ANSI S12.60 in 2002 there were no known performance standards or special controls for Sound Field amplification systems.

Test procedures to obtain FCC (Federal Communications Commission) approval are in accordance with good engineering practices and in accordance with FCC Rules, Part 15, Subpart A, 15, 19 (a) (3) and (C) Code of Federal Regulations (CFR 47).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Phonic Ear, Inc.
c/o Mr. Michael L. Gibbs
Regulatory Affairs & QMS Manager
Corporate Headquarters
3880 Cypress Drive
Petaluma, CA 94928

Re: K043090
Trade/Device Name: Phonic Ear Sound Field Group Amplification Systems
Regulation Number: 21 CFR 874.3320
Regulation Name: Group Hearing Aid, Group Auditory Trainer
Regulatory Class: Class II
Product Code: LZI
Dated: November 30, 2004
Received: December 2, 2004

Dear Mr. Gibbs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K043090

Device Name: Phonic Ear Sound Field Group Amplification Systems

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Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Over-the-Counter Use

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K043090