DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

Ear Technology Corp.
c/o Mr. Rick Gilbert
106 E. Watauga Ave.
Johnson City, TN 37601

Re: K062404
Trade/Device Name: TransEar® Bone Conduction Hearing Aid
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid (Bone Conduction)
Regulatory Class: II
Product Code: LXB
Dated: August 10, 2006
Received: August 17, 2006

Dear Mr. Gilbert:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, 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: K062404

Device Name: TransEar® Bone Conduction Hearing Aid

Indications for Use:

TransEar® is intended for individuals with single sided deafness or unaidable unilateral hearing loss, with single sided deafness being defined as an ear having one or more of the following characteristics:

1) Profound sensorineural hearing loss of such magnitude that there is no perceived benefit from an air conduction hearing aid coupled to the same ear.
2) A hearing loss greater than 50 dB HTL at frequencies of 500 Hz – 4000 Hz with speech recognition ability less than 50% when presented in quiet, at a 40 dB sensation level relative to the user's speech reception threshold.
3) A hearing loss greater than 50 dB HTL at frequencies of 500 Hz – 4000 Hz with a small dynamic range, for loudness less than 20 dB for amplified speech, which makes the use of an air conduction hearing aid intolerable to the user.

The "better" cochlea should have pure tone air conduction thresholds 30 dB HTL or better for the test frequencies of 500, 1000, 2000 Hz and 60 dB HTL or better at 3000 Hz.

For individuals with a "better" ear that exhibits a mixed or conductive hearing loss, bone conduction thresholds should be 30 dB HTL or better for the test frequencies of 500, 1000, 2000 Hz and 60 db HTL or better at 3000 Hz.

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

(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)

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

510(k) Number