DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1997

Louis T. Gnecco, M.S.E.E.
Vice President
Better Hearing, Inc.
112 Elden Street
Herndon, VA 20170-4809

Re: K971298
Better Hearing, Inc. Model L-1 Hearing Aid
Dated: June 28, 1997
Received: July 8, 1997
Regulatory Class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Mr. Gnecco:

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.

While your device has been deemed substantially equivalent to other legally marketed hearing aids, please be advised that the claim regarding electromagnetic compatibility with digital cellular telephones has not been adequately substantiated and cannot be permitted at this time. Based upon inadequate EMC test data submitted in this 510(k), use of such a claim may result in the device being misbranded.

We would be pleased to work with you regarding the development of a testing protocol to substantiate an appropriate claim. We will include this subject as an agenda item for our upcoming meeting on July 24.

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".

We look forward to meeting with you in the spirit of understanding and cooperation.

Sincerely yours,

for David A. Gregory

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

JUL 23 1997

BETTER HEARING, INC.

K971298

Mr. H. Sauberman, FDA: June 28, 1997

Enclosure 3:

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name: BETTER HEARING, INC. model L-1 Hearing Aid

Type: Behind-The-Ear (BTE)

Classification: Air Conduction Hearing Aid 77ESD Class 1
CFR 874.3300.

Intended Use: To amplify and transmit sound to the ear.

Substantially Equivalent to: Other medium power linear BTE hearing aids.
~~Differs in that it is compatible with digital cellular telephones.~~

See SE Letter 7/20/97 JYC

Registration Number: Applied for on April 4, 1997

Materials: Manufactured from materials commonly used in the industry.

Technical Characteristics: Hearing Aid has been tested
per ANSI S3.22 1987.

Fits: Mild to moderate hearing losses.

Power: Size 675 Battery

510(k) Number (if known): APPLIED FOR: APR 4, 1997

Device Name: BETTER HEARING INC. Model L-1 Hearing Aid

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
___1. Slight	___1. High Frequency - Precipitously Sloping	___1. Low tolerance To Loudness
X 2. Mild	X 2. Gradually Sloping	___2. _____
X 3. Moderate	X 3. Reverse Slope	___3. _____
___4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1. ~~Compatible with digital cellular telephones.~~ See SE letter 7/20/97 JJC

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971298

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)