Safety And Effectiveness Summary - Bellman Response model 1050.

K970340

MAR 26 1997

Name of device:	Bellman Response model 1050
Type of device:	Air Conduction Assistive Listening Device. Personal Amplifier.
Intended use:	To assist in conversation, meetings and TV-listening by amplifying sound.
Features:	Adjustable volume control, Microphone/Telephone/Off switch, Gain, Treble and AGC adjustment trimmers, Internal/External microphone switch.
Assembly:	Assembled from standard components widely used in electronic products.
Technical Characteristics:	Technical specifications comply with ANSI S3.22-1987.
Controls:	Volume control, Microphone/Telephone/Off switch, Internal/External microphone switch and sound adjustment trimmers similar to those used on other assistive listening devices/Personal amplifiers.
Power:	Standard alkaline AAA (or LR03) size battery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Martin Eriksson
Engineer, Product Development
Bellman AB
Gustaf Werners Gata 2
S-421 32 Vastra Frolunda
Gothenburg, Sweden

JAN 1 0 2017

Re: K970340
Trade/Device Name: Bellman Response Model 1050 Assistive Listening Device
Regulation Number: 21 CFR 874.3320
Regulation Name: Group hearing aid or group auditory trainer
Regulatory Class: Class II
Product Code: LZI
Dated: January 17, 1997
Received: January 29, 1997

Dear Mr. Eriksson:

This letter corrects our substantially equivalent letter of March 26, 1997.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for 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

510(k) Number (if known): K970340

Device Name: Bellman Response, model 1050

Indications For Use:

A. General Indications:

The indications for use of the assistive listening device in this submission is to amplify sound for individuals with impaired hearing. The device is indicated for individuals with hearing loss 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	___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.

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. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970340

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

Not restricted

Over-the-Counter Use ✓