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510(k) SUMMARY

**HEARING INNOVATIONS INCORPORATED
MODEL WMR
BEHIND-THE-EAR (BTE)
HEARING INSTRUMENT**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: September 16, 1996

Name of Device and Name/Address of Sponsor

Model WMR Behind-The-Ear (BTE) Hearing Instrument

Hearing Innovations Incorporated
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Tucson, Arizona 85718

Classification Name

The model WMR Behind-The-Ear (BTE) Hearing Instrument is among those devices commonly referred to as air conduction hearing aids. These devices have been classified by the Ear, Nose and Throat Classification Panel as Class I devices set forth in 21 CFR 874.3300

Action Taken to Comply With Performance Standards

Performance data for this submission has been obtained in accordance with the test procedures of the American National Standard Specification of Hearing Aid Characteristics, ANSI S3.22-1987 (Revision of S3.22-1982).

Intended Use

Intended to be used as a wearable sound amplifying device to compensate for mild to severe hearing loss.

Product Description

The Model WMR BTE is a dual-channel, wide-dynamic range input compression instrument which allows for loudness correction by changing compression ratios within the two bands. The WMR separates incoming signals into high and low frequency bands which can be independently compressed prior to recombination and amplification. The electronics for the hearing instrument are contained in a custom plastic case.

The Model WMR BTE features three adjustable trimmers that can only be adjusted by the dispenser to meet individual patient requirements. The user may adjust the gain (loudness) of the hearing instrument by rotating the volume control dial to his/her most comfortable listening level. This hearing instrument does not require a special fitting system; however, the trimmer controls may only be adjusted by an authorized hearing aid dispenser, NOT by the consumer. Notes to this effect are included in the User Instruction Booklet included in this submission.

- 1) The crossover frequency between the low band and high band channels;
- 2) High band compression ratio;
- 3) Low band compression ratio

Predicate Devices

The Model WMR BTE Hearing Instrument is substantially equivalent to the following successfully reviewed devices:

ReSound Personal Hearing System-BT2	K943788
3M 8260 Programmable Instruments	K935095
3M 8200 P Multipro BTE	K953543
Siemens Full Dynamic Range Compression BTE	K951828

Technological Characteristics and Substantial Equivalence

Like its predicate devices, the Model WMR is a behind-the-ear (BTE) air conduction hearing aid which utilizes a standard hearing aid microphone and transduces sound into an electrical signal. The signal is processed, amplified and converted back to sound by a standard hearing aid receiver.

The technological characteristics available in the Model WMR BTE are similar to those in the predicate devices. Like the ReSound Personal Hearing System-BT2 predicate, the Model WMR BTE offers wide dynamic range compression; the Model WMR BTE offers two bands of compression. The 3M predicates offer a two channel programmable AGC aid with flexibility to change the crossover frequency like the Model WMR. While the predicate devices utilize digital control of an analog signal, the Model WMR BTE is adjusted by the dispenser using the three available trimmers: the crossover frequency between the low band and high band channels; high band compression ratio; low band compression ratio. No special fitting system is required to program the device.

There are no technological differences between the Model WMR BTE and its predicate devices to raise any new issues of safety or efficacy.