

K96 4669

Appendix B

DEC 26 1986

Summary of Safety and Effectiveness

Device Name: Dahlberg Power BTE

Device Type: BTE Hearing Aid

Classification: Air Conduction Hearing Aid (77ESD), Class I.

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

Substantially Equivalent to: Miracle-Ear HL BTE which was cleared for distribution under document control number K926092.

Registration Number: 2110592

Materials: The hearing aid cases will be manufactured from materials that are commonly used in the industry.

Assembly: The hearing aid will be assembled utilizing similar assembly practices as Dahlberg's current products.

Technical Characteristics: Dahlberg utilizes the ANSI S3.22-1987 methodology to test and obtain performance data for hearing aids.

Fit: Moderate to profound as dictated by the individual users audiogram.

Power: Zinc-Air size 675 battery.