

K970262

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Summary of Safety and Effectiveness

Device Name: Dahlberg Hearing Aid with multi-channel compression circuit

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: Dahlberg multi-channel compression BTE hearing aids which were cleared for distribution under document control number K964530.

Registration Number: 2110592

Materials: The hearing aid shells 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: Mild to severe as dictated by the individual users audiogram.

Power: Zinc-Air size 13 battery.