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15964419

Summary of Safety and Effectiveness

Device Name: Dahlberg Sharp Plus and BILL Hearing Aids

Device Type: CIC, ITC and ITE Hearing Aids

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

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

**Substantially
Equivalent to:** Miracle-Ear Sharp Plus canal hearing aids which were cleared for distribution under 510(k) #K935265.

**Registration
Number:** 2110592

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

**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: Battery size dependent on hearing aid model.