

K964794

DEC 23 1996

**Summary of Safety and Effectiveness**

**Device Name:** Dahlberg K-AMP 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 K-AMP Circuits which was cleared for distribution under document control number K954941.

**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:** Mild to severe as dictated by the individual users audiogram.

**Power:** Zinc-Air size 13 battery.