

JAN 27 1997

Appendix B

K965057

Summary of Safety and Effectiveness

Device Name: Audiotone A-554H 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: Audiotone model A-54SR which was cleared for distribution under document control number K941122.

Registration Number: 2110592

Materials: The hearing aid cases 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: Zinc-Air size 13 battery.