



K961827

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Summary of Safety And Effectiveness
for DSD K-AMP Option

The summary of information, new product to present products demonstrates substantial equivalence as required by the "Safe Medical Devices Act (SMDA)" of 1990. The design follows traditional principles of operation for hearing aid instruments. This device is manufactured and assembled with equivalent manufacturing practices and performance guidelines. Performance of this instrument meets requirements specified by ANSI S-3.22 1987. User controls and methods are similar to other products currently on the market. Sound processing for this instrument is also similar to devices presently marketed by Qualitone.