

Ethical Hearing Instruments, Inc.

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K904680

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Safety and Effectiveness

**DRAERD 510 (k) Summary/Statement Certification
for Ethical ComfortAid Hearing Aid.**

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 Aids. The device is manufactured and assembled with equivalent manufacturing practices and performance guidelines. Performance of this instrument meets requirements specified by ANSI S3.2-1987. User controls and methods are similar to others currently being marketed.