

K964244

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## **SAFETY AND EFFECTIVENESS SUMMARY - Starkey Custom Sequel Programmable, K Amp Programmable**

**NAME OF DEVICE:** Starkey Custom Sequel Programmable and K Amp programmable air conduction hearing aids.

**TYPE OF DEVICE:** Custom fit air conduction hearing aids available as ITE, ITC, or CIC -- Substantially equivalent to the Starkey CE-9 Resolution programmable hearing aid, (K933989)

**INTENDED USE:** To assist in compensating for hearing loss by amplifying sound pressure waves as they enter the ear.

**FEATURES:** Adjustable hearing aid volume control, color coding for left and right instruments, 6 programmable options: Low cut, High cut, Gain control, Compression ratio, Threshold knee, and Output limiting for Sequel, or Loudness Boost for K Amp.

**ASSEMBLY:** Assembled from standard components that are widely used in hearing aid devices throughout the industry.

**TECHNICAL CHARACTERISTICS:** Technical specifications comply with ANSI S3.22-1987

**FIT:** Frequency response varying based on the needs of the patient. Tolerances are maintained to a  $\pm 4$  dB range for SSPL and slope, with +6 dB, -4 dB for gain.

**CONTROLS:** Volume controls, similar to those used on other hearing aid devices. Switches may be incorporated as options require. Any switches are similar to those used in other hearing aid devices.

**POWER:** Standard hearing aid batteries.

**SUMMARY-- STARKEY Custom Sequel Programmable and K Amp Programmable SUBSTANTIAL EQUIVALENCE**

The Starkey Custom Sequel Programmable and K-Amp Programmable are air conduction hearing aids that are designed to be all-in-the-ear hearing aids. This form of hearing aid is intended to be received by a Hearing Health Professional in a completed form, not being intended for final assembly.

The Starkey Custom Sequel Programmable and K-Amp Programmable aids are substantially equivalent to the Starkey CE-9 Resolution(K933989). The Starkey Custom Sequel Programmable and K-Amp Programmable are available as ITE, ITC, and CIC hearing aids. They are programmed by using the Pro-Connect (K932269) or Hi-Pro systems with the PFS software. They may also be programmed with the Rastronics pr3000 with the PFS software, or the PFS 6000.

**CE 9 RESOLUTION**

- Available as ITE
- 6 Programmable Features
- Programmed with Trilogy Desktop or Pro-Connect
- Non Volatile Memory
- Full range programmability from 105dB SSPL to 125dB SSPL, 30dB gain to 60dB gain
- Class D output instrument with compression available
- Memory holds two responses which can be switched by user

**Custom Sequel, K Amp Programmable**

- Available as ITE, ITC, CIC
- 6 Programmable Features
- Programmed with Pro-Connect or Hi-Pro systems and PFS software
- Non Volatile Memory
- Full range programmability from 100dB SSPL to 117dB SSPL, 20dB gain to 50dB gain
- Totally programmable class D compression instrument
- Programmable with pr3000 with PFS software or PFS 6000