

K940978

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SAFETY AND EFFECTIVENESS SUMMARY - Euroline A-312 Series

NAME OF DEVICES: A-312 K-Amp, A-312 ISP, A-312 OSP, A-312 Linear.
K-Amp, ISP, OSP, and Linear are the current circuit options available. Other circuit options may be added as a result of consumer demand. These circuit options would not affect the safety or effectiveness of the A-312 Series.

TYPE OF DEVICE: Air Conduction Behind-the-Ear hearing aids - Substantially equivalent to the Starkey Euroline A Series BTE Hearing Aids (K940978)

INTENDED USE: To assist in compensating for hearing loss by amplifying sound as it comes near the ear .

FEATURES: Adjustable volume control, Microphone/Telephone/Off switch on all models.

ASSEMBLY: Assembled from standard components that are widely used in hearing aid devices.

TECHNICAL CHARACTERISTICS: Technical specifications comply with ANSI S3.22-1987 and IEC 118-0 1983

FIT: For conductive and/or sensori-neural hearing loss where BTE type hearing aids are preferred or required.

CONTROLS: Volume control, Mic/Telephone/Off switch similar to those used on other hearing aid devices. Potentiometers and may be incorporated as options require. Any pots or switches are similar to those used in other BTE hearing aid devices.

POWER: Standard 312 or equivalent hearing aid battery.

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SUMMARY -- Starkey Euroline A-312 Series SUBSTANTIAL EQUIVALENCE

The Starkey Euroline A-312 Series BTE Hearing aids are behind-the-ear air conduction 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 Euroline A-312 Series BTE Hearing aids are substantially equivalent to the Starkey Laboratories Euroline A Series BTE Hearing aids.

Euroline A-312 Series

- BTE Air conduction
- Adjustable Gain Control
- Telephone/Mic/Off Switch
- Adjustable potentiometers for low frequency, peak clipping, threshold kneepoint
- 312 or equiv Battery
- Miniature size
- Colors: Grey housing and Brown panel or Brown housing and Brown panel

Euroline A Series

- BTE Air conduction
- Adjustable Gain Control
- Telephone/Mic/Off Switch
- Adjustable potentiometers for low frequency, peak clipping or AGC, and high frequency attenuation
- 13 or equiv Battery
- Miniature size
- Colors: Choice of 15 different skin tone shades for the side panels of the case.

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