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oticon

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: PrimoFocus Compact

TYPE OF DEVICE: BTE Hearing Aid

INTENDED USE: To amplify and deliver sound to the ear.

FEATURES: 47 Db HFA gain, single band compression amplifier with dual time constants and variable compression threshold, utilizes class D output amplifier.

ASSEMBLY: Assembled from standard electronic hearing aid components mounted together with a custom microchip/hybrid.

TECHNICAL CHARACTERISTICS: Technical specifications are in accordance with ANSI Standards S3.22-1987

FITTING CRITERIA: Frequency response, compression threshold, gain and SSPL 90 is dictated by individual audiometric and patient history data.

ADJUSTMENTS/ CONTROLS: All parameters are adjusted via manual controls.

POWER SOURCE: Standard type 13 battery.

A USER INSTRUCTIONAL BROCHURE AND ADJUSTMENT INSTRUCTIONS ARE SUPPLIED WITH EACH HEARING AID.