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oticon

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

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: DigiFocus Compact (DFC)

TYPE OF DEVICE: Behind The Ear Hearing Aid

INTENDED USE: To amplify and deliver sound to the ear

FEATURES: DigiFocus is a seven band, two channel fully automatic hearing instrument which utilizes true digital signal processing (DSP). True DSP allows for precise, seven band frequency shaping and a unique and complex compression system utilizing syllabic compression in the lower frequency channel (below 1500Hz) and nonsyllabic compression in the higher frequency channel (above 1500Hz). 54 dB HFA gain.

ASSEMBLY: Assembled from standard electronic hearing aid components mounted together with custom microchips on flexfilm.

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

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

ADJUSTMENTS/ CONTROLS: All parameters are digitally programmed via software. The hearing aid has a manual OTM switch.

POWER SOURCE: Standard type 13 battery.

A USER INSTRUCTIONAL BROCHURE, INCLUDING ANSI TECHNICAL DATA IS SUPPLIED WITH EACH HEARING AID