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DEC 12 1996

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 ITE (DFI)

TYPE OF DEVICE: In 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 1500 Hz) and nonsyllabic compression in the higher frequency channel (above 1500Hz). 42 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 OtiSet software using the standard NOAH platform. The hearing aid may have an optional T-M switch.

POWER SOURCE: Standard size 312 battery.

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