

K964683 DIGIFOCUS ITEDec 12, 1996
20 days to decisionK964683 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k964683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Nov 22, 1996
Decision date	Dec 12, 1996
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oticon, Inc.
Location	Somerset, NJ, US
Contact	PREBEN BRUNVED
510(k) history	9 submissions · 9 cleared · 1993-1997

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