

K946045 OTICONJan 30, 1995
49 days to decisionK946045 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k946045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 12, 1994
Decision date	Jan 30, 1995
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k946045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 5, 2026