

K972373 OVATION HDPJul 29, 1997
34 days to decisionK972373 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k972373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jun 25, 1997
Decision date	Jul 29, 1997
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orsonique, Inc.
Location	Laval, Quebec, CA
Contact	EUGENE ALEXANDRESCU
510(k) history	6 submissions · 6 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972373/> 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