

K963818 OVATION AGC-2Oct 28, 1996
35 days to decisionK963818 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k963818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Sep 23, 1996
Decision date	Oct 28, 1996
Days to decision	35 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

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