

K974211 OPUS 2 - FULL CONCHA SERIES - ITEDec 15, 1997
35 days to decisionK974211 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k974211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Nov 10, 1997
Decision date	Dec 15, 1997
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bernafon-Maico, Inc.
Location	Eden Prairie, MN, US
Contact	RAY ENROTH
510(k) history	9 submissions · 9 cleared · 1996-1998

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