

K971080 MAICO MA52Jun 6, 1997
73 days to decisionK971080 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k971080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Mar 25, 1997
Decision date	Jun 6, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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