

K933800 FLUOROFILM(R)Jun 24, 1994
324 days to decisionK933800 · Product code: **EMX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k933800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon, Epistaxis (EMX)
Date received	Aug 4, 1993
Decision date	Jun 24, 1994
Days to decision	324 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	American Custom Medical, Inc.
Location	Lubbock, TX, US
Contact	BRUCE G RUEFER
510(k) history	5 submissions · 5 cleared · 1994-1997

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