

K821584 EPISTAXIS CATHETER/KITJun 14, 1982
13 days to decisionK821584 · Product code: **EMX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k821584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon, Epistaxis (EMX)
Date received	Jun 1, 1982
Decision date	Jun 14, 1982
Days to decision	13 days
Third-party review	No

APPLICANT

Company	Bivona Medical Technologies
Location	Mchenry, IL, US
510(k) history	50 submissions · 50 cleared · 1978-1995

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821584/>; 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 May 26, 2026