

**K921199 EPISTAXIS NASAL BALLOON CATHETER**Jul 8, 1992  
118 days to decisionK921199 · Product code: **EMX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k921199/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon, Epistaxis (EMX)
Date received	Mar 12, 1992
Decision date	Jul 8, 1992
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smith &amp; Nephew Richards, Inc.</b>
Location	Memphus, TN, US
Contact	THOMAS CRAIG
510(k) history	87 submissions · 72 cleared · 1990-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921199/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 21, 2026