

**K945554 EPISTAXIS BALLOON CATHETER WITH PACKING**Feb 17, 1995  
95 days to decisionK945554 · Product code: **EMX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k945554/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon, Epistaxis (EMX)
Date received	Nov 14, 1994
Decision date	Feb 17, 1995
Days to decision	95 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ultracell Medical Technologies, Inc.</b>
Location	North Stonington, CT, US
Contact	GEORGE P KORTEWEG
510(k) history	24 submissions · 24 cleared · 1992-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945554/> 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 June 29, 2026