

**K964701 MITRAFLEX PIGMENTED WOUND DRESSING**Feb 7, 1997  
74 days to decisionK964701 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k964701/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 25, 1996
Decision date	Feb 7, 1997
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Polymedica Industries, Inc.</b>
Location	Golden, CO, US
Contact	JULIE CHAFFEE
510(k) history	16 submissions · 13 cleared · 1993-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964701/> 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