

**K964042 EXTRESAFE PHLEBOTOMY**Jun 6, 1997  
241 days to decisionK964042 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k964042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 8, 1996
Decision date	Jun 6, 1997
Days to decision	241 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Specialized Health Products, Inc.</b>
Location	Bountiful, UT, US
Contact	WILLIAM E MCKAY
510(k) history	4 submissions · 4 cleared · 1996-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964042/> 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 July 2, 2026