

**K935776 SHARPSAFE, CAT. NO. 4126**Feb 28, 1994  
87 days to decisionK935776 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k935776/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 3, 1993
Decision date	Feb 28, 1994
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smiths Industries Medical Systems, Inc.</b>
Location	Keene, NH, US
Contact	TIMOTHY J TALCOTT
510(k) history	22 submissions · 19 cleared · 1993-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935776/> 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 25, 2026