

K935628 SHARPSAFE CAT. NO. 4127Feb 4, 1994
73 days to decisionK935628 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k935628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 23, 1993
Decision date	Feb 4, 1994
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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