

K935843 BE-SAFEJun 3, 1994
177 days to decisionK935843 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k935843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 8, 1993
Decision date	Jun 3, 1994
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mathis-Koolpe, Inc.
Location	Elkins Park, PA, US
Contact	ROBERT P MATHIS, M.D.
510(k) history	1 submissions · 1 cleared · 1994-1994

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