

K934561 ONE TIME VIAL ACCESS SPIKEFeb 10, 1994
142 days to decisionK934561 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k934561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 21, 1993
Decision date	Feb 10, 1994
Days to decision	142 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Icu Medical, Inc.
Location	Walker, MI, US
Contact	SALVADORE F PALMARES
510(k) history	66 submissions · 65 cleared · 1984-2026

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