

K934591 CLAVE VIAL ACCESS SPIKEFeb 16, 1994
145 days to decisionK934591 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k934591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 24, 1993
Decision date	Feb 16, 1994
Days to decision	145 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934591/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026