

K082836 ICU MEDICAL UNIVERSAL SINGLE-USE SPIKESFeb 25, 2009
152 days to decisionK082836 · Product code: **FMG** · General Hospital
Source: <https://www.510kdatabase.net/k082836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stopcock, I.v. Set (FMG)
Date received	Sep 26, 2008
Decision date	Feb 25, 2009
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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