

**K964435 PRIMARY IV SET**Apr 2, 1997  
148 days to decisionK964435 · Product code: **FMG** · General Hospital  
Source: <https://www.510kdatabase.net/k964435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stopcock, I.v. Set (FMG)
Date received	Nov 5, 1996
Decision date	Apr 2, 1997
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icu Medical, Inc.</b>
Location	Walker, MI, US
Contact	RICHARD WATERS
510(k) history	66 submissions · 65 cleared · 1984-2026

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