

**K032854 UNOMEDICAL MONICA INFUSION SET**Oct 9, 2003  
27 days to decisionK032854 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k032854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 12, 2003
Decision date	Oct 9, 2003
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Unomedical A/S</b>
Location	Roskilde, DK
Contact	JOHN M LINDSKOG
510(k) history	13 submissions · 13 cleared · 2003-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032854/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026