

**K851103 VASCULAR IMPLANT ACCESS NEEDLE SET**Jul 16, 1985  
119 days to decisionK851103 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k851103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 19, 1985
Decision date	Jul 16, 1985
Days to decision	119 days
Third-party review	No

**APPLICANT**

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Company	<b>Baxter Healthcare Corp</b>
Location	Mchenry, IL, US
Contact	ROGER A LEROUX
510(k) history	505 submissions · 496 cleared · 1977-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851103/>; 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 17, 2026