

**K852831 NON-KOR ACCESS KITS**Sep 19, 1985  
79 days to decisionK852831 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k852831/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SD
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 2, 1985
Decision date	Sep 19, 1985
Days to decision	79 days
Third-party review	No

**APPLICANT**

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Company	<b>Creative Care Systems, Inc.</b>
Location	Walker, MI, US
Contact	WILLIAM STEINHARDT
510(k) history	7 submissions · 6 cleared · 1984-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852831/>, 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 27, 2026