

**K854547 MONOJECT STERILE M200 ALUMINUM/M250  
POLYPROPYLENE**Feb 4, 1986  
83 days to decisionK854547 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k854547/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 13, 1985
Decision date	Feb 4, 1986
Days to decision	83 days
Third-party review	No

**APPLICANT**

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Company	<b>Sherwood Medical Co.</b>
Location	Mchenry, IL, US
Contact	FRANK J FUCILE
510(k) history	191 submissions · 177 cleared · 1976-1998

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854547/>; 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 14, 2026