

**K854549 MONOJECT STERILE M400 PLASTIC&STERILE M401  
ALUMINU**Feb 4, 1986  
83 days to decisionK854549 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k854549/>**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        | FUCILE, JR.                               |
| 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/k854549/>; 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