

**K912111 MODIFIED VERSION IMPLANTABLE VASCULAR ACCESS SYSTE**Oct 8, 1991  
148 days to decisionK912111 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k912111/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 13, 1991
Decision date	Oct 8, 1991
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gerard Medical Enterprises, Inc.</b>
Location	Mchenry, IL, US
Contact	CAYER, JR.
510(k) history	8 submissions · 6 cleared · 1981-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912111/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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