

**K811009 PREFILLED PULSATOR SYRINGE**Jun 12, 1981  
58 days to decisionK811009 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k811009/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 15, 1981
Decision date	Jun 12, 1981
Days to decision	58 days
Third-party review	No

**APPLICANT**

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Company	<b>Concord Laboratories, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.concordlabs.com">https://www.concordlabs.com</a>
510(k) history	42 submissions · 38 cleared · 1976-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k811009/>; 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