

**K861686 NOVOPEN SYSTEM (INSULIN SYRINGE)**Jan 21, 1987  
264 days to decisionK861686 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k861686/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 2, 1986
Decision date	Jan 21, 1987
Days to decision	264 days
Third-party review	No

**APPLICANT**

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Company	<b>Squibb-Novo, Inc.</b>
Location	Princeton, NJ, US
Contact	STEPHANIE RAIS
510(k) history	2 submissions · 2 cleared · 1987-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861686/>; 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 July 9, 2026