

**K100005 BD PEN NEEDLE**Apr 15, 2010  
101 days to decisionK100005 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k100005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 4, 2010
Decision date	Apr 15, 2010
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Becton, Dickinson and Co.</b>
Location	Sarasota, FL, US
Contact	James Haynes
510(k) history	6 submissions · 6 cleared · 2001-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100005/> 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 June 3, 2026