

**K950466 B-D ULTRA-FINE II PEN NEEDLE**May 11, 1995  
97 days to decisionK950466 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k950466/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 3, 1995
Decision date	May 11, 1995
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bd Becton Dickinson Vacutainer Systems Preanalytic</b>
Location	Washington, DC, US
Contact	PETER ZURLO
510(k) history	632 submissions · 625 cleared · 1976-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950466/> 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 21, 2026