

**K133100 CAREFINE PEN NEEDLE**Jan 23, 2014  
115 days to decisionK133100 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k133100/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 30, 2013
Decision date	Jan 23, 2014
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Facet Technologies</b>
Location	Kennesaw, GA, US
Contact	MARY ANN KINARD
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133100/> 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 7, 2026