

**K152877 SureFine Pen Needle**Jun 7, 2016  
251 days to decisionK152877 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k152877/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 30, 2015
Decision date	Jun 7, 2016
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shina Med Corporation</b>
Location	Anseong-Si, KR
Contact	SUNG-SOON PARK
510(k) history	7 submissions · 7 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152877/> 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 2, 2026