

**K152410 Top Fine Pen Needle**Feb 2, 2016  
160 days to decisionK152410 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k152410/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 26, 2015
Decision date	Feb 2, 2016
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medexel Co.,Ltd</b>
Location	Anseong-Si, KR
Contact	CHA DONG IK
510(k) history	3 submissions · 3 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152410/> 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 27, 2026