

**K161950 Common Type Insulin Pen Needle, Safety Type Insulin Pen Needle**May 11, 2017  
300 days to decisionK161950 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k161950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 15, 2016
Decision date	May 11, 2017
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Promised Hangzhou Meditech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Keshin Hu
510(k) history	34 submissions · 34 cleared · 2017-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161950/> Data sourced from FDA 510(k) public records (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 1, 2026