

**K170846 Disposable Insulin Pen Needle**Dec 13, 2017  
267 days to decisionK170846 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k170846/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 21, 2017
Decision date	Dec 13, 2017
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Caina Technology Co., Ltd.</b>
Location	Jiangyin, CN
Contact	Jun Lu
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170846/> 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 31, 2026