

**K180259 Sterile Hypodermic Needle for Single Use**May 18, 2018  
108 days to decisionK180259 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k180259/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 30, 2018
Decision date	May 18, 2018
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Shenli Medical Production Co., Ltd.</b>
Location	Changzhou City, CN
Contact	Tina Cai
510(k) history	3 submissions · 3 cleared · 2017-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Irc</b>
Contact	Charles Mack

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180259/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026