

**K213183 Safety Insulin Pen Needles**Oct 14, 2022  
380 days to decisionK213183 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k213183/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 29, 2021
Decision date	Oct 14, 2022
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Kindly Medical Devices Co., Ltd.</b>
Location	Wenzhou, CN
Contact	Yong Zhang
510(k) history	5 submissions · 5 cleared · 2018-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Mind-Link Business Consulting Co., Ltd.</b>
Contact	Alice Huang

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/k213183/> 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 May 26, 2026