

**K233037 Sterile Hypodermic Needles for Single Use**Dec 12, 2023  
78 days to decisionK233037 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k233037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 25, 2023
Decision date	Dec 12, 2023
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Kindly Medical Device Co., Ltd.</b>
Location	Wenzhou City, CN
Contact	Zhang Qian
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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