

**K220129 Promisemed X-Safety Pen Needle**Sep 19, 2022  
244 days to decisionK220129 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k220129/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 18, 2022
Decision date	Sep 19, 2022
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Vee Care (Asia) Limited</b>
Contact	Wei Shan Hsu

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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