

**K211242 Promisemed Sterile Hypodermic Syringes, Verifine  
Sterile Hypodermic Syringes**Sep 9, 2021  
136 days to decisionK211242 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k211242/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 26, 2021
Decision date	Sep 9, 2021
Days to decision	136 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)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211242/> 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 13, 2026