

K223453 Insulin SyringeMar 2, 2023
106 days to decisionK223453 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k223453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 16, 2022
Decision date	Mar 2, 2023
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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