

K193273 Insulin SyringeJan 5, 2021
406 days to decisionK193273 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k193273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 26, 2019
Decision date	Jan 5, 2021
Days to decision	406 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	Liqing Yang
510(k) history	34 submissions · 34 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Christy Young

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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