

K191853 Dual-Safety Pen NeedleSep 5, 2019
57 days to decisionK191853 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k191853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 10, 2019
Decision date	Sep 5, 2019
Days to decision	57 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	35 submissions · 35 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	Medtech Review, LLC
Contact	John Beasley

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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