

K221080 Sterile Safety Hypodermic Needles for Single UseOct 4, 2022
175 days to decisionK221080 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k221080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 12, 2022
Decision date	Oct 4, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sichuan Prius Biotechnology Co., Ltd.
Location	Yibin, CN
Contact	Yan Liu
510(k) history	9 submissions · 9 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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