

**K221069 Infusion Sets for Single Use with Needles**Nov 21, 2022  
223 days to decisionK221069 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k221069/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 12, 2022
Decision date	Nov 21, 2022
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
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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