

K202437 Infusion Sets for Single UseMar 25, 2022
577 days to decisionK202437 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k202437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 25, 2020
Decision date	Mar 25, 2022
Days to decision	577 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Suyun Medical Materials Co., Ltd.
Location	Shanghai, CN
Contact	Guangning Xu
510(k) history	2 submissions · 2 cleared · 2011-2022

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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