FDA 510(k) Premarket Notification

K221075 Infusion Sets for Single Use

CLEARED

Nov 21, 2022
223 days to decision

K221075 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k221075/

SUBMISSION DETAILS

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

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