

K220312 Polyfusion IV Administration SetsApr 12, 2023
434 days to decisionK220312 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k220312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 2, 2022
Decision date	Apr 12, 2023
Days to decision	434 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Poly Medicare Limited
Location	Jaipur, IN
Contact	Ramdas Sharma
510(k) history	6 submissions · 6 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Donawa Lifescience Consulting Srl
Contact	Roger Gray

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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