FDA 510(k) Premarket Notification

# K220312 Polyfusion IV Administration Sets

**CLEARED**

Apr 12, 2023
434 days to decision

K220312 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k220312/

## SUBMISSION DETAILS

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|---|---|
| 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 Medicure Limited** |
| Location | Jaipur, IN |
| Contact | Ramdas Sharma |
| 510(k) history | 6 submissions · 6 cleared · 2023-2026 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Donawa Lifescience Consluting Srl** |
| Contact | Roger Gray |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov