

K223101 BD Secondary Infusion SetMay 12, 2023
224 days to decisionK223101 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k223101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 30, 2022
Decision date	May 12, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Care Fusion
Location	Waukegan, IL, US
Contact	Paulina Davis
510(k) history	34 submissions · 29 cleared · 2010-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026