FDA 510(k) Premarket Notification

K223101 BD Secondary Infusion Set

CLEARED

May 12, 2023
224 days to decision

K223101 · Product code: **FPA** · General Hospital
Source: 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