FDA 510(k) Premarket Notification

K243529 Solution Administration Sets

CLEARED

Mar 14, 2025
120 days to decision

K243529 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k243529/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Nov 14, 2024
Decision date	Mar 14, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corporation**
Location	Round Lake, IL, US
Contact	Meaghan Bonn
510(k) history	61 submissions · 60 cleared · 2004-2025