

K243529 Solution Administration SetsMar 14, 2025
120 days to decisionK243529 · Product code: **FPA** · General HospitalSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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