

K203609 Intravascular Administration SetsSep 30, 2021
294 days to decisionK203609 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k203609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Dec 10, 2020
Decision date	Sep 30, 2021
Days to decision	294 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	Jeffrey E. Thompson
510(k) history	61 submissions · 60 cleared · 2004-2025

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