

K192366 Intravascular Extension Sets and AccessoriesJul 20, 2020
325 days to decisionK192366 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k192366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 30, 2019
Decision date	Jul 20, 2020
Days to decision	325 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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