

K161323 Solution Set for Epidural UseNov 30, 2016
203 days to decisionK161323 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k161323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 11, 2016
Decision date	Nov 30, 2016
Days to decision	203 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161323/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026