

**K161808 Solution Set with 1.2 Micron Air Eliminating Filter**Jun 21, 2017  
355 days to decisionK161808 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k161808/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 1, 2016
Decision date	Jun 21, 2017
Days to decision	355 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Healthcare Corporation</b>
Location	Round Lake, IL, US
Contact	John Lamela
510(k) history	61 submissions · 60 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161808/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026