

**K162820 AC3 Series IABP System**Mar 31, 2017  
175 days to decisionK162820 · Product code: **DSP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Oct 7, 2016
Decision date	Mar 31, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arrow International, Inc.</b>
Location	Reading, PA, US
Contact	Alifiya Jagmag
510(k) history	19 submissions · 17 cleared · 2003-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162820/> 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 June 18, 2026