

**K200634 Arrow FiberOptix Intra-Aortic Balloon Catheter Kit**Apr 9, 2020  
30 days to decisionK200634 · Product code: **DSP** · CardiovascularSource: <https://www.510kdatabase.net/k200634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Mar 10, 2020
Decision date	Apr 9, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arrow International, Inc.</b>
Location	Reading, PA, US
Contact	Apurva N. Gokhale
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/k200634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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