

**K190117 Fiberoptic IAB**Jun 13, 2019  
140 days to decisionK190117 · Product code: **DSP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190117/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Jan 24, 2019
Decision date	Jun 13, 2019
Days to decision	140 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	Niyati Boghani
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/k190117/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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