

K192238 AC3 Series Intra-Aortic Balloon Pump (IABP)Nov 12, 2019
85 days to decisionK192238 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k192238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 19, 2019
Decision date	Nov 12, 2019
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arrow International, Teleflex
Location	Chelmsford, MA, US
Contact	Deb Fleetham
510(k) history	1 submissions · 1 cleared · 2019-2019

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