

K232343 AC3™ Series IABPAug 30, 2023
26 days to decisionK232343 · Product code: **DSP** · CardiovascularSource: <https://www.510kdatabase.net/k232343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 4, 2023
Decision date	Aug 30, 2023
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arrow International, LLC
Location	Morrisville, NC, US
Contact	Sheila Payzant
Website	https://www.arrowintl.com
510(k) history	3 submissions · 3 cleared · 2023-2025

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