

**K250542 AC3™ Range™ Intra-Aortic Balloon Pump**Mar 26, 2025  
30 days to decisionK250542 · Product code: **DSP** · CardiovascularSource: <https://www.510kdatabase.net/k250542/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Feb 24, 2025
Decision date	Mar 26, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Arrow International, LLC</b>
Location	Morrisville, NC, US
Contact	Apurva Gokhale
Website	<a href="https://www.arrowintl.com">https://www.arrowintl.com</a>
510(k) history	3 submissions · 3 cleared · 2023-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250542/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026