

**K201112 AC3 IABP, AC3 Optimus IABP, AutoCAT2 Wave IABP,
AutoCAT2 IABP**May 27, 2020
30 days to decisionK201112 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k201112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Apr 27, 2020
Decision date	May 27, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arrow International, Inc.
Location	Reading, PA, US
Contact	Shajunath Nirupama
510(k) history	19 submissions · 17 cleared · 2003-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201112/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026