

**K993966 8FR. NARROWFLEX UNIVERSAL INTRA-AORTIC
BALLOON CATHETER**Feb 18, 2000
87 days to decisionK993966 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k993966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Nov 23, 1999
Decision date	Feb 18, 2000
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arrow Intl., Inc.
Location	Mchenry, IL, US
Contact	WILLIAM PAQUIN
510(k) history	110 submissions · 105 cleared · 1976-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993966/> 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 May 22, 2026