

**K963920 8 FR.-30CC NARROWFLEX INTRA-AORTIC BALLOON
CATHETER,**Jun 17, 1997
260 days to decisionK963920 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k963920/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Sep 30, 1996
Decision date	Jun 17, 1997
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963920/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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