

**K970229 ARROW TRANSSEPTAL SUPER ARROW-FLEX
PERCUTANEOUS SET**Feb 13, 1998
388 days to decisionK970229 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k970229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 21, 1997
Decision date	Feb 13, 1998
Days to decision	388 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/k970229/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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