K970229 ARROW TRANSSEPTAL SUPER ARROW-FLEX PERCUTANEOUS SET

CLEARED

Feb 13, 1998
388 days to decision

K970229 · 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