FDA 510(k) Premarket Notification

K993966 8FR. NARROWFLEX UNIVERSAL INTRA-AORTIC BALLOON CATHETER

CLEARED

Feb 18, 2000
87 days to decision

K993966 · 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