FDA 510(k) Premarket Notification

K963920 8 FR.-30CC NARROWFLEX INTRA-AORTIC BALLOON CATHETER,

CLEARED

Jun 17, 1997
260 days to decision

K963920 · 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