FDA 510(k) Premarket Notification

K892530 CATHETERS FOR BALLOON OCCLUSION FEMORAL ANGIOGRAPH

CLEARED

Sep 26, 1989
168 days to decision

K892530 · Product code: **DYG** · Cardiovascular
Source: https://www.510kdatabase.net/k892530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Apr 11, 1989
Decision date	Sep 26, 1989
Days to decision	168 days
Third-party review	No

APPLICANT

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