

K963865 8 FR. -30CC NARROWFLEX SHEATHLESS INTRA-AORTIC BALLOON CATHETER, PRODUCT NUMBER IAB-04830SSep 16, 1997
357 days to decisionK963865 · Product code: **DSP** · Cardiovascular
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Sep 24, 1996
Decision date	Sep 16, 1997
Days to decision	357 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

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