

K965209 ACAT 1 (ARROW CARDIAC ASSIST TECHNOLOGY 1)Jan 23, 1998
392 days to decisionK965209 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k965209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Dec 27, 1996
Decision date	Jan 23, 1998
Days to decision	392 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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