

**K963104 9.5 FR.- FLEXI-CATH INTRA-AORTIC AND CONTROL SYSTEM**Feb 4, 1997  
179 days to decisionK963104 · Product code: **DSP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k963104/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 9, 1996
Decision date	Feb 4, 1997
Days to decision	179 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963104/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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