FDA 510(k) Premarket Notification

K963104 9.5 FR.- FLEXI-CATH INTRA-AORTIC AND CONTROL SYSTEM

CLEARED

Feb 4, 1997
179 days to decision

K963104 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k963104/

SUBMISSION DETAILS

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

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