FDA 510(k) Premarket Notification

K991431 14 FR. HEMODIALYSIS TWO-LUMEN CATHETERIZATION KIT

CLEARED

May 26, 1999
30 days to decision

K991431 · Product code: **MPB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k991431/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Apr 26, 1999
Decision date	May 26, 1999
Days to decision	30 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