FDA 510(k) Premarket Notification

K963684 A2 PORT, DUAL LUMEN SYSTEM WITH DETACHED CATHETER, CATALOG # AP-01518 (MODIFIED)

CLEARED

Oct 24, 1996
73 days to decision

K963684 · Product code: **LJT** · General Hospital
Source: https://www.510kdatabase.net/k963684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Aug 12, 1996
Decision date	Oct 24, 1996
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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