FDA 510(k) Premarket Notification

K780532 PERCUTANEOUS SHEATH INTRODUCER KIT

CLEARED

Apr 21, 1978
17 days to decision

K780532 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k780532/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 4, 1978
Decision date	Apr 21, 1978
Days to decision	17 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k780532/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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