FDA 510(k) Premarket Notification

CLEARED

K011056 ARROW-TREROTOLA PERCUTANEOUS THROMBOLYTIC DEVICE OR PTD

Oct 24, 2001
201 days to decision

K011056 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k011056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Apr 6, 2001
Decision date	Oct 24, 2001
Days to decision	201 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