FDA 510(k) Premarket Notification

K122854 ARROW GLIDETHRU PEEL-AWAY SHEATH/DILATOR INTRODUCER

CLEARED

Jan 4, 2013
108 days to decision

K122854 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k122854/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 18, 2012
Decision date	Jan 4, 2013
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arrow International (Subsidiary of Teleflex Inc.)**
Location	Reading, PA, US
Contact	JULIE LAWSON
510(k) history	6 submissions · 6 cleared · 2012-2013