FDA 510(k) Premarket Notification

K122795 STINGRAY GUIDEWIRES

CLEARED

Nov 8, 2012
57 days to decision

K122795 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k122795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Sep 12, 2012
Decision date	Nov 8, 2012
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bridgepoint Medical**
Location	Orinda, CA, US
Contact	JILL MUNSINGER
510(k) history	14 submissions · 14 cleared · 2008-2012