FDA 510(k) Premarket Notification

K120881 MANTARAY GUIDEWIRES

CLEARED

Apr 18, 2012
26 days to decision

K120881 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k120881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 23, 2012
Decision date	Apr 18, 2012
Days to decision	26 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