FDA 510(k) Premarket Notification

K121398 CHARLIE GUIDEWIRE (REGULAR), CHARLIE GUIDEWIRE (STIFF)

CLEARED

Dec 13, 2012
218 days to decision

K121398 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k121398/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 9, 2012
Decision date	Dec 13, 2012
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidepath Medical, Inc.**
Location	Austin, TX, US
Contact	JOHN MITCHELL TATUM
510(k) history	1 submissions · 1 cleared · 2012-2012