FDA 510(k) Premarket Notification

K103377 CHARTER GUIDEWIRE MODEL 45-281, 45-282, 45-283

CLEARED

May 18, 2011
182 days to decision

K103377 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k103377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 17, 2010
Decision date	May 18, 2011
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Brivant, Ltd.**
Location	Galway, IE
Contact	TOMAS FUREY
510(k) history	7 submissions · 7 cleared · 2008-2012