FDA 510(k) Premarket Notification

K152456 CenterCross Ultra Catheter

CLEARED

Jan 26, 2016
151 days to decision

K152456 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k152456/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 28, 2015
Decision date	Jan 26, 2016
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roxwood Medical, Inc.**
Location	San Francisco, CA, US
Contact	Grace Li
510(k) history	8 submissions · 8 cleared · 2012-2017