FDA 510(k) Premarket Notification

K150187 ELITECROSS Support Catheter

CLEARED

May 19, 2015
112 days to decision

K150187 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k150187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jan 27, 2015
Decision date	May 19, 2015
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corporation, A Johnson & Johnson Company**
Location	Fremont, CA, US
Contact	Michelle Ragozzino Rodgers
510(k) history	1 submissions · 1 cleared · 2015-2015