FDA 510(k) Premarket Notification

K150836 OUTBACK Elite Re-Entry Catheter

CLEARED

Apr 29, 2015
30 days to decision

K150836 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k150836/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Mar 30, 2015
Decision date	Apr 29, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corporation, A Johnson & Johnson Co.**
Location	Fremont, CA, US
Contact	MICHELLE RAGOZZINO RODGERS
510(k) history	1 submissions · 1 cleared · 2015-2015