

**K083814 OUTBACK LTD RE-ENTRY CATHETER, MODEL:
OTB42120**Jan 13, 2009
22 days to decisionK083814 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k083814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Dec 22, 2008
Decision date	Jan 13, 2009
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cordis Corp., A Johnson & Johnson Co.
Location	Warren, NJ, US
Contact	KAREN WILK
510(k) history	5 submissions · 5 cleared · 2006-2014

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