

**K130911 RAPIDCROSS PTA RAPID EXCHANGE BALLOON
DILATATION CATHETER**

May 24, 2013
52 days to decision

K130911 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k130911/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 2, 2013
Decision date	May 24, 2013
Days to decision	52 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Ev3, Inc.
Location	Plymouth, MN, US
Contact	LAURA J LIND
510(k) history	35 submissions · 26 cleared · 2003-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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