

**K123544 RAPIDCROSS PTA RAPID EXCHANGE, BALLOON
DILATATION CATHETER**Feb 12, 2013
85 days to decisionK123544 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k123544/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Nov 19, 2012 |
| Decision date | Feb 12, 2013 |
| Days to decision | 85 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.netDevice record: <https://www.510kdatabase.net/k123544/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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