

K142654 Fortrex 0.035 OTW PTA Balloon CatheterOct 28, 2014
40 days to decisionK142654 · Product code: **LIT** · Cardiovascular
Source: <https://www.510kdatabase.net/k142654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 18, 2014
Decision date	Oct 28, 2014
Days to decision	40 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Rupali Gupta
510(k) history	88 submissions · 85 cleared · 2010-2026

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