

K143561 ELM PTA Balloon Dilatation CatheterMay 19, 2015
154 days to decisionK143561 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k143561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Dec 16, 2014
Decision date	May 19, 2015
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	O&apos;Connell Regulatory Consultants, Inc.
Location	North Reading, MA, US
Contact	Maureen O'Connell
510(k) history	1 submissions · 1 cleared · 2015-2015

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