

K152665 PolarCath Peripheral Dilatation SystemOct 26, 2015
39 days to decisionK152665 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k152665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Sep 17, 2015
Decision date	Oct 26, 2015
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nucyro Vascular, LLC
Location	Sunnyvale, CA, US
Contact	MIKE FOURKAS
510(k) history	1 submissions · 1 cleared · 2015-2015

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