

K161427 Pirouette 035Jul 30, 2016
68 days to decisionK161427 · Product code: **LIT** · Cardiovascular
Source: <https://www.510kdatabase.net/k161427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 23, 2016
Decision date	Jul 30, 2016
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arravasc Limited
Location	Galway, IE
Contact	Aoife Donoghue
510(k) history	2 submissions · 2 cleared · 2015-2016

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