

**K172033 Pirouette High Pressure (HP)**Aug 31, 2017  
57 days to decisionK172033 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k172033/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 5, 2017
Decision date	Aug 31, 2017
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arravasc, Ltd.</b>
Location	Galway, IE
Contact	Carmel Doherty
510(k) history	2 submissions · 2 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172033/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 31, 2026