

**K163114 Sapphire II PRO**Jan 5, 2017  
59 days to decisionK163114 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163114/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Nov 7, 2016
Decision date	Jan 5, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orbusneich Medical, Inc.</b>
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	4 submissions · 4 cleared · 2011-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163114/> 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 June 2, 2026