

K162209 Sapphire NC PlusOct 6, 2016
62 days to decisionK162209 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k162209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Aug 5, 2016
Decision date	Oct 6, 2016
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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