

K103657 SAPPHIREAug 9, 2011
237 days to decisionK103657 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k103657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 15, 2010
Decision date	Aug 9, 2011
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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