

K200269 Sapphire II PROMar 4, 2020
29 days to decisionK200269 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k200269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Feb 4, 2020
Decision date	Mar 4, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orbusneich Medical Trading, Inc.
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	7 submissions · 7 cleared · 2018-2020

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