

K211807 Sapphire NC 24Oct 14, 2021
125 days to decisionK211807 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k211807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jun 11, 2021
Decision date	Oct 14, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	OrbusNeich Medical (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Daniel Zhang
510(k) history	9 submissions · 9 cleared · 2020-2026

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