

K233499 Sapphire NC ULTRA Coronary Dilatation CatheterAug 16, 2024
290 days to decisionK233499 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k233499/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Oct 31, 2023
Decision date	Aug 16, 2024
Days to decision	290 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	Jerry Cheung
510(k) history	9 submissions · 9 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233499/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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