FDA 510(k) Premarket Notification

K211807 Sapphire NC 24

CLEARED

Oct 14, 2021
125 days to decision

K211807 · Product code: **LOX** · Cardiovascular
Source: 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