FDA 510(k) Premarket Notification

K233505 Sapphire ULTRA Coronary Dilatation Catheter

CLEARED

Aug 15, 2024
289 days to decision

K233505 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k233505/

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 15, 2024
Days to decision	289 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