

K241025 JADE PLUS PTA Balloon Dilatation CatheterJun 11, 2024
57 days to decisionK241025 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k241025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 15, 2024
Decision date	Jun 11, 2024
Days to decision	57 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

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