

K201794 JadeJul 28, 2020
28 days to decisionK201794 · Product code: **LIT** · Cardiovascular
Source: <https://www.510kdatabase.net/k201794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jun 30, 2020
Decision date	Jul 28, 2020
Days to decision	28 days
Third-party review	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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