

**K202231 JADE**Dec 10, 2020  
125 days to decisionK202231 · Product code: **LIT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k202231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 7, 2020
Decision date	Dec 10, 2020
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OrbusNeich Medical (Shenzhen) Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Daniel Zhang
510(k) history	9 submissions · 9 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202231/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026