

**K172331 Type I, Type II, Type III, Type IV**Mar 2, 2018  
212 days to decisionK172331 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172331/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 2, 2017
Decision date	Mar 2, 2018
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lepu Medical Technology (Beijing) Co., Ltd.</b>
Location	Beijing, CN
Contact	Xiangdan Jin
510(k) history	7 submissions · 6 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172331/> 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 31, 2026