FDA 510(k) Premarket Notification

K172331 Type I, Type II, Type III, Type IV

CLEARED

Mar 2, 2018
212 days to decision

K172331 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k172331/

SUBMISSION DETAILS

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

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