

**K211530 PathBuilder Steerable Introducer**Feb 8, 2022  
267 days to decisionK211530 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211530/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 17, 2021
Decision date	Feb 8, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shanghai Microport EP Medtech Co., Ltd.</b>
Location	Shanghai, CN
Contact	Tian Xia
510(k) history	4 submissions · 4 cleared · 2022-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211530/> 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