

**K212625 PathBuilder Transseptal Needle**Mar 23, 2022  
217 days to decisionK212625 · Product code: **DRC** · CardiovascularSource: <https://www.510kdatabase.net/k212625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Aug 18, 2021
Decision date	Mar 23, 2022
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212625/> 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