

K251838 Introducer Sheath SetOct 21, 2025
127 days to decisionK251838 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k251838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 16, 2025
Decision date	Oct 21, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiocyte Medical(Suzhou) Co., Ltd.
Location	Suzhou, CN
Contact	Ling Li
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251838/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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