

K254248 Introducer Sheath SetApr 23, 2026
115 days to decisionK254248 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k254248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 29, 2025
Decision date	Apr 23, 2026
Days to decision	115 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	Siyu Chen
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254248/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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