

**K242248 Introducer Sheath Kits**Aug 22, 2024  
22 days to decisionK242248 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k242248/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 31, 2024
Decision date	Aug 22, 2024
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Beijing Demax Medical Technology Co.,Ltd</b>
Location	Guangzhou, CN
Contact	Nicole Liu
510(k) history	4 submissions · 4 cleared · 2015-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Hlongmed Biotech Co., Ltd.</b>
Contact	Long Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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