

**K260606 Echo Large Bore Introducer Sheath**Apr 29, 2026  
64 days to decisionK260606 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k260606/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 24, 2026
Decision date	Apr 29, 2026
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Echo Medical, LLC</b>
Location	Irvine, CA, US
Contact	Steve Geist
Website	<a href="https://echomedical.com">https://echomedical.com</a>
510(k) history	1 submissions · 1 cleared · 2026-2026

Echo Medical, LLC is a dynamic medical services company incorporated and registered in the Kingdom of Bahrain, with a manufacturing facility in Irvine, US. The company specializes in providing innovative pharmaceutical products, food supplements, and advanced medical devices designed to enhance patient health and quality of life across the MENA region. Echo Medical has received FDA 510(k) clearance from total submission. The company focuses exclusively on Cardiovascular devices. The latest clearance was received in 2026, demonstrating active regulatory engagement and curr...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Landon Consulting, LLC</b>
Contact	Anna Landon

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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