

**K213492 Dib UltraNav Transseptal Catheter System**Mar 24, 2022  
143 days to decisionK213492 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 1, 2021
Decision date	Mar 24, 2022
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dib Ultrana Medical, LLC</b>
Location	El Paso, TX, US
Contact	Lowry Barfield
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>The Tamarack Group – Mpls, LLC</b>
Contact	Noelle Sutton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213492/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026