

**K192106 AcQRef Introducer Sheath**Sep 3, 2019  
29 days to decisionK192106 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192106/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 5, 2019
Decision date	Sep 3, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acutus Medical, Inc.</b>
Location	Carlsbad, CA, US
Contact	Serena Sanginithirath
510(k) history	24 submissions · 24 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192106/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026