

**K211100 AcQGuide MAX Steerable Sheath**May 14, 2021  
31 days to decisionK211100 · Product code: **DRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211100/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Apr 13, 2021
Decision date	May 14, 2021
Days to decision	31 days
Third-party review	Yes
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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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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