

K220047 AcQCross Qx Integrated Transseptal Dilator/NeedleFeb 8, 2022
34 days to decisionK220047 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k220047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jan 5, 2022
Decision date	Feb 8, 2022
Days to decision	34 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Acutus Medical, Inc.
Location	Carlsbad, CA, US
Contact	Sarah Clay
510(k) history	24 submissions · 24 cleared · 2017-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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