FDA 510(k) Premarket Notification

CLEARED

K193509 AcQGuide Flex with AcQCross QX, AcQGuide Mini with AcQCross QX

Jan 17, 2020
30 days to decision

K193509 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k193509/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 18, 2019
Decision date	Jan 17, 2020
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acutus Medical, Inc.**
Location	Carlsbad, CA, US
Contact	Greg Geissinger
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