FDA 510(k) Premarket Notification

K211100 AcQGuide MAX Steerable Sheath

CLEARED

May 14, 2021
31 days to decision

K211100 · Product code: **DRA** · Cardiovascular
Source: https://www.510kdatabase.net/k211100/

SUBMISSION DETAILS

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

Company	**Acutus Medical, Inc.**
Location	Carlsbad, CA, US
Contact	Serena Sanginthirath
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