FDA 510(k) Premarket Notification

K201076 Anchor Dual Lumen Guidewire Catheter

CLEARED

Aug 6, 2020
106 days to decision

K201076 · Product code: **QJP** · Neurology
Source: https://www.510kdatabase.net/k201076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Apr 22, 2020
Decision date	Aug 6, 2020
Days to decision	106 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aqure Medical, Inc.**
Location	Rogers, MN, US
Contact	Jie Xia
510(k) history	1 submissions · 1 cleared · 2020-2020

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