FDA 510(k) Premarket Notification

K214106 QuikPass Catheter

CLEARED

Jan 28, 2022
30 days to decision

K214106 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k214106/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 29, 2021
Decision date	Jan 28, 2022
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Traverse Vascular, Inc.**
Location	Solana Beach, CA, US
Contact	Greg Geissinger
510(k) history	1 submissions · 1 cleared · 2022-2022

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