FDA 510(k) Premarket Notification

K193194 CrossTorq 14 Guidewire

CLEARED

Dec 13, 2019
24 days to decision

K193194 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k193194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 19, 2019
Decision date	Dec 13, 2019
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Scientia Cardio Access, LLC**
Location	West Valley City, UT, US
Contact	Amy McManus
510(k) history	1 submissions · 1 cleared · 2019-2019

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