FDA 510(k) Premarket Notification

K203521 FineCross M3

CLEARED

Mar 3, 2021
92 days to decision

K203521 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k203521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 1, 2020
Decision date	Mar 3, 2021
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ashitaka Factory of Terumo Corporation**
Location	Fujinomiya Shizuoka, JP
Contact	Vaibhav Sivaramakrishan
510(k) history	3 submissions · 3 cleared · 2016-2021

REGULATORY CONSULTANT

Consulting firm	**Terumo Medical Corporation**
Contact	Vaibhav Sivaramakrishan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov