FDA 510(k) Premarket Notification

K213949 VASSALLO GT 018 Floppy

CLEARED

Jun 30, 2022
195 days to decision

K213949 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k213949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 17, 2021
Decision date	Jun 30, 2022
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Filmecc Co., Ltd.**
Location	Hagoya-Shi, JP
Contact	Toshiya Osawa
510(k) history	5 submissions · 5 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**CardioMed Device Consultants, LLC**
Contact	Candace Cederman

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