

K213949 VASSALLO GT 018 FloppyJun 30, 2022
195 days to decisionK213949 · 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](https://accessdata.fda.gov)

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