

K203533 VASSALLO GTApr 21, 2021
140 days to decisionK203533 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k203533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 2, 2020
Decision date	Apr 21, 2021
Days to decision	140 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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