

**K222631 VASSALLO GT EXT**Oct 26, 2022  
56 days to decisionK222631 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k222631/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 31, 2022
Decision date	Oct 26, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>CardioMed Device Consultants, LLC</b>
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)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222631/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026