

**K232578 VASSALLO GT 018 G12**Oct 11, 2023  
47 days to decisionK232578 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k232578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 25, 2023
Decision date	Oct 11, 2023
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VASSALLO GT 018 G30

**APPLICANT**

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Company	<b>Filmec Co. , Ltd.</b>
Location	Hagoya-Shi, JP
Contact	Toshiya Osawa
510(k) history	2 submissions · 2 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Cardiomed Device Consultants, LLC</b>
Contact	Meagan Fagan

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232578/> 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