FDA 510(k) Premarket Notification

K232578 VASSALLO GT 018 G12

CLEARED

Oct 11, 2023
47 days to decision

K232578 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k232578/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Cardiomed Device Conultants, LLC**
Contact	Meagan Fagan

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