FDA 510(k) Premarket Notification

K222631 VASSALLO GT EXT

CLEARED

Oct 26, 2022
56 days to decision

K222631 · Product code: **DQX** · Cardiovascular
Source: 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	**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