

K242337 FlowGuide (FG60F)Apr 17, 2025
253 days to decisionK242337 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k242337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 7, 2024
Decision date	Apr 17, 2025
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GuidionShort (GS60F)

APPLICANT

Company	Imds Operations B.V.
Location	Roden, Drenthe, NL
Contact	Edwin Schulting
510(k) history	8 submissions · 8 cleared · 2012-2025

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