

K250751 DualView CatheterJul 17, 2025
127 days to decisionK250751 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k250751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Mar 12, 2025
Decision date	Jul 17, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corporation
Location	Shibuya-Ku, Tokyo, JP
Contact	Patrick McDonald
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Terumo Medical Corporation
Contact	Patrick McDonald

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

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