

K252309 PerQseal IntroducersOct 23, 2025
91 days to decisionK252309 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k252309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 24, 2025
Decision date	Oct 23, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vivasure Medical Limited
Location	Galway, IE
Contact	Tom Maguire
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Fernando Aguel

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

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