

K261242 SimplGuideJun 25, 2026
71 days to decisionK261242 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k261242/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 15, 2026
Decision date	Jun 25, 2026
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pendracare
Location	Leek, NL
Contact	Erendira Rodriguez
510(k) history	2 submissions · 2 cleared · 2025-2026

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