

K250972 Primum Hydrophilic Guiding CatheterJun 29, 2025
90 days to decisionK250972 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k250972/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 31, 2025
Decision date	Jun 29, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pendracare
Location	Leek, NL
Contact	Erendira Rodriguez
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250972/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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