FDA 510(k) Premarket Notification

K250972 Primum Hydrophilic Guiding Catheter

CLEARED

Jun 29, 2025
90 days to decision

K250972 · Product code: **DQY** · Cardiovascular
Source: 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