

K210431 ReCrossJul 15, 2021
153 days to decisionK210431 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k210431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 12, 2021
Decision date	Jul 15, 2021
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imds Operations B.V.
Location	Roden, Drenthe, NL
Contact	Edwin Schulting
510(k) history	8 submissions · 8 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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