

K200324 NHancer RxAug 6, 2020
178 days to decisionK200324 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k200324/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 10, 2020
Decision date	Aug 6, 2020
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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