FDA 510(k) Premarket Notification

K260559 NHanceIT

CLEARED

Aug 14, 2026
176 days to decision

K260559 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k260559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 19, 2026
Decision date	Aug 14, 2026
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**IMDS Operation B.V.**
Location	Roden, NL
Contact	Edwin Schulting
510(k) history	1 submissions · 1 cleared · 2026-2026