FDA 510(k) Premarket Notification

K191229 TrapIt

CLEARED

Jan 21, 2020
258 days to decision

K191229 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k191229/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 8, 2019
Decision date	Jan 21, 2020
Days to decision	258 days
Third-party review	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.net
Device record: https://www.510kdatabase.net/k191229/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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