FDA 510(k) Premarket Notification

K210110 Guidion

CLEARED

Mar 31, 2021
71 days to decision

K210110 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k210110/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 19, 2021
Decision date	Mar 31, 2021
Days to decision	71 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