FDA 510(k) Premarket Notification

K121077 NHANCER

CLEARED

Dec 21, 2012
256 days to decision

K121077 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k121077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 9, 2012
Decision date	Dec 21, 2012
Days to decision	256 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k121077/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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