FDA 510(k) Premarket Notification

K241611 ShapeIT (SI014135)

CLEARED

Sep 3, 2024
90 days to decision

K241611 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k241611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 5, 2024
Decision date	Sep 3, 2024
Days to decision	90 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