

**K241611 ShapeIT (SI014135)**Sep 3, 2024  
90 days to decisionK241611 · Product code: **DQY** · CardiovascularSource: <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	<b>Imds Operations B.V.</b>
Location	Roden, Drenthe, NL
Contact	Edwin Schulting
510(k) history	8 submissions · 8 cleared · 2012-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241611/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026