

K260459 VANES Delivery System (VDS)Apr 6, 2026
54 days to decisionK260459 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k260459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 11, 2026
Decision date	Apr 6, 2026
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zoll Respicardia, Inc.
Location	Minnetonka, MN, US
Contact	Abby VanHaren
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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