April 6, 2026

Zoll Respicardia, Inc.
Kevin Bentley
Vice President, Regulatory & Quality
12400 Whitewater Dr.
Suite 150
Minnetonka, Minnesota 55343

Re: K260459
Trade/Device Name: VANES Delivery System (VDS)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 11, 2026
Received: February 11, 2026

Dear Kevin Bentley:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2026.04.06 15:42:11 -04'00'

Finn Donaldson
Team Lead
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260459

Device Name
VANES Delivery System (VDS)

Indications for Use *(Describe)*
For the introduction of various types of pacing or defibrillation leads and catheters.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #:

510(k) Summary

Prepared on: 2026-02-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ZOLL Respicardia, Inc.
Applicant Address	12400 Whitewater Drive Suite 150 Minnetonka MN 55343 United States
Applicant Contact Telephone	715-572-4952
Applicant Contact	Ms. Abby VanHaren
Applicant Contact Email	abby.vanharen@zoll.com
Correspondent Name	ZOLL Respicardia, Inc.
Correspondent Address	12400 Whitewater Drive Suite 150 Minnetonka MN 55343 United States
Correspondent Contact Telephone	612-286-5999
Correspondent Contact	Mr. Kevin Bentley
Correspondent Contact Email	kbentley@zoll.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VANES Delivery System (VDS)
Common Name	Catheter introducer
Classification Name	Introducer, Catheter
Regulation Number	870.1340
Product Code(s)	DYB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152116	5.5 F Worley Advanced LVI Lateral Vein Introducer	DYB

Device Description Summary

21 CFR 807.92(a)(4)

The VANES Delivery System consists of an outer introducer catheter, 2 inner subselection catheters, a slitter and transvalvular introducer tool (TVI). The outer and inner catheters are the only components of the system that have contact to the patient during the venous introduction of devices such as guidewires, catheters and pacing leads. The outer introducer catheter is intended to access the venous system either alone or in a telescopic assembly with subselection catheters. The outer and inner catheters serve as a conduit to guide devices (guidewires, stimulation leads, and catheters) or to deliver contrast medium into specific branches of the venous system. The outer and inner catheters come with distal end curve configurations to facilitate sub-selective access to angulated lateral vein branches. The VANES Delivery System is designed as a single use device and for short term application (< 24 hours). Only medical doctors and medical personnel, who are well trained in venous introduction and navigation techniques should apply these introducers.
The VANES Delivery System outer and inner catheters have a shaft design with two (2) stiffness segmentations. The shaft is reinforced by a metal braid from the proximal end until approximately 0.130 inches from the distal end. The proximal end of the outer catheter is

equipped with a hemostasis valve that reduces the risk of blood loss and air embolism and a side-port with 3-way stopcock to allow fluid infusion and contrast injection.
There are various versions of the outer introducer distal end curves that are used according to the anatomy of the present patient's vasculature. The distal soft tip has a radius on the outer diameter and the distal tip further contains a polymeric x-ray marker for enhanced visibility under fluoroscopy. The materials of construction are primarily polymers.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

For the introduction of various types of pacing or defibrillation leads and catheters.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The VANES Delivery System indications for use are identical to the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The VANES Delivery System is identical to Merit Medical's Worley Advanced LVI Lateral Vein Introducer and shares the same materials, manufacturing process, manufacturing facility, packaging process, sterilization cycle, and technological characteristics. The only difference between the VANES Delivery System and the Merit Worley Advanced LVI Lateral Vein Introducer is the working length of the inner and outer catheters. The predicate Worley Advanced LVI Lateral Vein Introducer outer guide catheter is 62-cm, and single inner catheter is 75-cm. In contrast, the subject device VANES Delivery System outer guide catheter is 30-cm, and dual inner subselection catheters are 47-cm.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench testing conducted on the subject device VANES Delivery System:
- Dimensional verification
- Torque Performance
- Kink Resistance
- Peak Tensile Force
- Leakage Testing
- Corrosion Resistance
- Particulate Testing

No animal and clinical studies were provided in this 510k.

Nonclinical tests demonstrate that the VANES Delivery System is substantially equivalent to the legally marketed Worley Lateral Vein Introducer.