March 25, 2026

Spectrum Vascular
Sharon Klugewicz
Senior VP, Quality and Regulatory Affairs
50 Main St.
Suite 1000
White Plains, New York 10606

Re: K254278
Trade/Device Name: Arterial Pressure Monitoring Set/Tray
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: February 24, 2026
Received: February 24, 2026

Dear Sharon Klugewicz:

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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K254278

Device Name
Arterial Pressure Monitoring Set/Tray

Indications for Use *(Describe)*
The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients.
- 2.5 French catheters are intended for patients from birth and older.
- 3.0 and 4.0 French catheters are intended for patients aged 1 year and older.
- 5.0 French catheters are intended for patients aged 12 years and older.

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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1. SUBMITTER INFORMATION

Applicant:	Spectrum Vascular
Contact:	Ms. Sharon Klugewicz
Phone:	516-425-4446
Email:	sklugewicz@spectrumvascular.com
Address	50 Main Street, Suite 1000 White Plains, NY 10606

2. CORRESPONDENT INFORMATION

Contact:	Ms. Sharon Klugewicz
Title:	Senior VP, Quality and Regulatory Affairs
Firm:	Spectrum Vascular 50 Main Street, Suite 1000 White Plains, NY 10606
Phone:	516-425-4446
Email:	sklugewicz@spectrumvascular.com

3. DATE PREPARED: MARCH 24, 2026

4. DEVICE INFORMATION

Device Name:	Arterial Pressure Monitoring Set/Tray
Common Name:	Diagnostic intravascular catheter
Regulation Number:	21 CFR 870.1200
Regulation Name:	Diagnostic intravascular catheter
Product Code:	DQO
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Primary Predicate Device Name:	Arterial Pressure Monitoring Set/Tray
510(k) Number:	K180846
Manufacturer:	Cook Incorporated

Secondary Predicate Device Name:	Arterial Pressure Monitoring Set/Tray
510(k) Number:	K180792
Manufacturer:	Cook Incorporated

6. DEVICE DESCRIPTION

The Arterial Pressure Monitoring Set/Tray is intended to be used for arterial pressure monitoring and blood sampling. The pressure monitoring catheter is inserted into the vasculature using the Seldinger technique. Based on the device length, the subject device may gain access via the radial artery, femoral artery, or distal aorta.

The Arterial Pressure Monitoring Set/Tray is comprised of a pressure monitoring catheter, wire guide, entry access needle, and syringe. The Arterial Pressure Monitoring Set/Tray is supplied sterile and intended for one-time use.

7. INDICATIONS FOR USE

The Arterial Pressure Monitoring Set/Tray is intended for arterial blood pressure monitoring and blood sampling in adult and pediatric patients.

- 2.5 French catheters are intended for patients from birth and older.
- 3.0 and 4.0 French catheters are intended for patients aged 1 year and older.
- 5.0 French catheters are intended for patients aged 12 years and older.

8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Other than the change in ink as noted in Table 1, the subject device is identical to the primary and secondary predicate devices.

Table 1: Technological Comparison to Predicate Devices

	Primary Predicate Device (K180846)	**Secondary Predicate Device (K180792)**	**Subject Device**
Regulation	21 CFR 870.1200	21 CFR 870.1200	21 CFR 870.1200
Product Code	DQO	DQO	DQO
Classification	Class II	Class II	Class II
Catheter Insertion Method	Percutaneously via Seldinger technique	Percutaneously via Seldinger technique	Percutaneously via Seldinger technique
Catheter Shaft Material	Polyethylene Ethylene-Vinyl Acetate Polyurethane *Ink Marking: UVA Ink (Color #1 Black)*	Nylon *Ink Marking: UVA Ink (Color #1 Black)*	Polyethylene Ethylene-Vinyl Acetate Polyurethane *Ink Marking: UVA Ink (TPC 980 Black Ink)*

	Primary Predicate Device (K180846)	Secondary Predicate Device (K180792)	Subject Device
Catheter Hub Material	Polyethylene Polyurethane	Nylon	Polyethylene Polyurethane Nylon
Catheter Outer Diameter	2.5, 3.0, 4.0 French	5.0 French	2.5, 3.0, 4.0, 5.0 French
Catheter Length	2.5, 4.0, 5.0, 6.0, 8.0, 12.0 cm	15 cm	2.5, 4.0, 5.0, 6.0, 8.0, 12.0, 15 cm
Catheter Lumen Design	Single lumen	Single lumen	Single lumen
Catheter Distal End	Straight tip	Straight tip	Straight tip
Dilator Shaft Material	Polyethylene	N/A	Polyethylene
Wire Guide Material	Stainless Steel	Stainless Steel	Stainless Steel
Wire Guide Diameter	0.015, 0.018, 0.021, 0.035 inch	0.035 inch	0.015, 0.018, 0.021, 0.035 inch
Packaging	Tray w/ Tyvek Lidstock	Tray w/ Tyvek Lidstock	Tray w/ Tyvek Lidstock
Single Use?	Yes	Yes	Yes
Sterilization Method	EtO	EtO	EtO
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The catheter of the subject device is identical to the Arterial Pressure Monitoring Set/Tray cleared in K180846 and K180792 with the exclusion of the marker ink. Additional biocompatibility testing on the subject device was conducted in accordance with the ISO 10993 series.

Electrical Safety

Not applicable. The subject device contains no electrical components, generates no electrical emissions, and uses no electrical energy of any type.

Electromagnetic Compatibility (EMC)

Not applicable. The subject device contains no electrical components, generates no electrical emissions, and uses no electrical energy of any type.

Software

Not applicable. The subject device contains no software.

Performance Testing

An additional ink legibility performance test was conducted to demonstrate that the device meets its design requirements and performs as intended.

10. CONCLUSION

The results of the performance testing described above demonstrate that the Arterial Pressure Monitoring Set/Tray perform equivalently as compared to the primary and secondary predicate devices and supports a determination of substantial equivalence.