July 30, 2025

Spectrum Vascular
Sharon Klugewicz
Chief Operating Officer / SVP Regulatory Affairs
50 Main Street
Suite 1000
White Plains, New York 10606

Re: K250724
Trade/Device Name: Intraosseous Infusion Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 30, 2025
Received: June 30, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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.

Submission Number *(if known)*

K250724

Device Name

Intraosseous Infusion Needles

Indications for Use *(Describe)*

Intraosseous Infusion Needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.

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

2. CORRESPONDENT INFORMATION

Contact:	Sharon Klugewicz
Title:	Chief Operating Officer/Sr. VP Regulatory Affairs
Firm:	Spectrum Vascular

3. DATE PREPARED: JULY 29, 2025

4. DEVICE INFORMATION

Device Name:	Intraosseous Infusion Needles
Common Name:	Hypodermic single lumen needle
Regulation Number:	880.5570
Regulation Name:	Hypodermic single lumen needle
Product Code:	FMI
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Device Name:	Cook® Intraosseous Infusion Needle
Common Name:	Hypodermic single lumen needle
510(k) Number:	K160887
Manufacturer:	Cook Medical

6. DEVICE DESCRIPTION

The Intraosseous Infusion Needles are intended for use as an alternative to intravenous access during pediatric emergencies, permitting infusion of drugs and fluids.

Intraosseous Infusion Needles consist of two basic components - the needle (composed of a knob, a stylet luer-lock, and a beveled stylet) and the cannula (comprised of a hub, a base plate, and a cannula shaft). The cannula attaches to the needle by the stylet luer-lock and is supplied attached and ready to use. The Intraosseous Infusion Needles are available in the following configurations:

Intraosseous Infusion Needle (with Dieckmann Modification – Standard Hub Design)

Cannula Gauge	Cannula/Stylet Length (cm)	Stylet Length (cm)	Stylet Bevel Style	Hub Material
14	3.0	4.6	Trocar	Clear Polycarbonate
16	2.5	4.2	Trocar	Clear Polycarbonate
	3.0	4.65		
	4.0	5.65		
18	2.5	4.2	Trocar	Pink Polycarbonate
	3.0	4.65		

7. INDICATIONS FOR USE

Intraosseous Infusion Needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Intraosseous Infusion Needles are identical to the Cook Intraosseous Infusion Needles. No changes have been made to the design of the device. This 510(k) is submitted to address changes to the sterilization process parameters and location.

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device** K160887
Regulation	880.5570	880.5570
Product Code	FMI	FMI
Classification	II	II
Indications for Use	Intraosseous Infusion Needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.	Cook Intraosseous Infusion Needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.

	Proposed Device	**Predicate Device** K160887
Cannula Materials		
Hub material	Polycarbonate	Nickel plated brass or polycarbonate
Base plate materials	Polycarbonate	Nickel plated brass or polycarbonate
Cannula shaft material	Stainless steel	Stainless steel
Cannula shaft diameter (gauge)	14, 16, 18	14, 15.5, 16, 18
Cannula shaft length (cm)	2.5, 3.0, 4.0	2.5, 3.0, 4.0
Needle Material		
Knob material	Nylon 6 (grey)	Nylon 6 (grey)
Stylet Luer-lock material	Polypropylene	Nickel plated brass or polypropylene
Beveled stylet material	Stainless steel	Stainless steel
Stylet length (cm)	4.2, 4.6, 4.65, 5.65	4.2, 4.6, 4.65, 4.7, 5.51, 5.6, 5.65, 5.7, 6.8, 7.0
Packaging	PETG tray/Tyvek	PETG tray/Tyvek
Sterilization	EtO	EtO
SAL	10^{-6}	10^{-6}

Discussion of Similarities and Differences

The change in the sterilization process (e.g., lower EO concentration, cycle parameters, and location), as well as the change in name from the Cook Intraosseous Infusion Needles to the Intraosseous Infusion Needles, and chosen configurations, do not raise new or different questions of safety and effectiveness when compared to the predicate device.

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The medical device in its final finished form is identical to the Cook® Intraosseous Infusion Needle in formulation, processing, sterilization method, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Electrical Safety

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

Electromagnetic Compatibility (EMC)

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

Software

Not applicable. The device contains no software.

Performance Testing

The following performance testing was conducted to validate changes to the sterilization cycle parameters:

- Ethylene Oxide Sterilization Performance Qualification
- Evaluation of ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals

No additional performance testing was conducted because the design of the subject device is identical to the predicate, K160887.

Reference Standards conformed to:

- ANSI/AAMI/ISO 11135 :2014, BS EN ISO 11135: Sterilization of health care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices
- ISO 10993-7:2008, Amd. 1:2019: Biological evaluation of medical devices— Part 7: Ethylene oxide sterilization residuals

10. CONCLUSION

The results of the performance testing described above demonstrate that the modified sterilization cycle for the subject device does not raise new or different questions of safety and effectiveness when compared to the predicate device, and the subject device is substantially equivalent to the predicate device.