May 2, 2025

SkyDance Vascular, Inc.
Scott Pease
Sr. VP, Reg. Affairs & Quality Assurance
3058 Millcreek Road
Pleasant Grove, Utah 84062

Re: K250292
Trade/Device Name: OSPREY Midline Closed IV Catheter System (OspreyEDC-F20)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: April 3, 2025
Received: April 4, 2025

Dear Scott Pease:

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,

David Wolloscheck, Ph.D.
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)*

K250292

Device Name

OSPREY Midline Closed IV Catheter System (OspreyEDC-F20)

Indications for Use *(Describe)*

OSPREY Midline Closed IV Catheter System (OspreyEDC) is an intravascular catheter intended to be inserted into the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The OSPREY Midline Closed IV Catheter System (OspreyEDC) is suitable for use with power injectors rated for a maximum of 325 psi when connected to male luer lock.

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.

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K250292 - 510(k) SUMMARY

SkyDance Vascular, Inc. – OSPREY PERIPHERAL IV Catheter System

Submitter

SkyDance Vascular, Inc.
3058 Millcreek Road
Pleasant Grove, UT 84062

Contact Phone: (m) 678-689-8010

Contact Person: Scott Pease, Sr. VP, Regulatory Affairs & Quality Assurance (scott.pease@skydancevascular.com)

Date Prepared: May 1, 2025

Name of Device: OSPREY Midline Closed IV Catheter System (OspreyEDC-F20)

Common or Usual Name: Short-Term, less than 30 days intravascular catheter Intravascular

Classification Name: Catheter

Regulatory Class: Class II

Product Code / Regulation: FOZ / 21 CFR § 880.5200

Predicate Device(s): Predicate – K231626 (OSPREY Closed IV Catheter System (OspreyV2)) – SkyDance Vascular, Inc.

Indications for Use

OSPREY Midline Closed IV Catheter System (OspreyEDC) is an intravascular catheter intended to be inserted into the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The OSPREY Midline Closed IV Catheter System (OspreyEDC) is suitable for use with power injectors rated for a maximum of 325 psi when connected to male luer lock.

Device Description

The OSPREY Midline Closed IV Catheter System (OspreyEDC) has a usable (deployed) catheter length of 3.25 inches. The device is a single use, sterile intravascular catheter designed to be inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously for short-term (<30 days) use. The device is constructed with a clear housing having integrated wings and ribs to assist with its handling, a beveled needle that allows the catheter to be deployed through it and the needle fully and permanently passively retracts into the housing when the catheter hub with its integrated extension tube, including an incorporated pinch clamp, female luer with porous (vent) plug is fully advanced via the wire slider with integrated stainless steel guidewire. The device is placed in a thermal formed tray that goes into a Tyvek pouch providing the sterile barrier.

Principles of Operation

The OSPREY Midline Closed IV Catheter System (OspreyEDC) design deploys the catheter by passing it through its integrated access needle. Once the access needle achieves the desired venipuncture the user can quickly visualize blood through the housing's integrated flash window and immediately begin advancing the catheter, pink catheter hub with its integrated extension tube having a pinch clamp, female luer with porous (vent) plug and guidewire through the access needle via the pink wire slider. Upon fully advancing the catheter and pink catheter hub via the pink wire slider within the proximal end of the device housing it simultaneously activates the passive needle retraction of the access needle within the device housing. Once the catheter and pink catheter hub is fully deployed the pink wire slider, wire slider track and guidewire are removed and appropriately disposed. Since the catheter is deployed through the access needle, the OspreyEDC catheter tip design is optimized to facilitate off-axis delivery of infusate. Additionally, the OspreyEDC is suitable for use with power injectors when connected to male luer lock.

Technological Characteristics Comparison to Predicate

The OSPREY Midline Closed IV Catheter System (OpsreyEDC) is similar to the predicate device, OSPREY Closed IV Catheter System (K231626). Each of the devices have the following characteristics in common: 1) they are short term catheters, 2) they are radiopaque catheters, 3) they are peripheral catheters, 4) they are disposable, single use catheters, 5) they provide a shielding mechanism for the used needle, 6) incorporates an integrated extension tube, including a pinch clamp, and female luer with porous (vent) plug, 7) has the ability to be used with a power injector.

Table VII - I: Comparison Table of Subject Device to Predicate Device

Attribute	Subject – OSPREY Midline Closed IV Catheter System (OspreyEDC)	Predicate – OSPREY Closed IV Catheter System (K231626)	Substantial Equivalence
Classification	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	**Identical**
Indications for Use	OSPREY Midline Closed IV Catheter System (OspreyEDC) is an intravascular catheter intended to be inserted into the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The OSPREY Midline Closed IV Catheter System (OspreyEDC) is suitable for use with power injectors rated for a maximum of 325 psi when connected to male luer lock.	OSPREY Closed IV Catheter System (OspreyV2) is an intravascular catheter intended to be inserted into the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The OSPREY Closed IV Catheter System (OspreyV2) is suitable for use with power injectors rated for a maximum of 325 psi when connected to male luer lock..	**Identical**
Critical Procedural Steps	Remove the device from the packaging and inspect before use. Insert needle into the target vein and observe blood flashback	Remove the device from the packaging and inspect before use. Insert needle into the target vein and observe blood flashback	**Different** Subject device instructions for use (IFU) is expanded to include instructions regarding the

Attribute	Subject – OSPREY Midline Closed IV Catheter System (OspreyEDC)	Predicate – OSPREY Closed IV Catheter System (K231626)	Substantial Equivalence
	response. Advance catheter into the vein while maintaining needle position. Activate the spring-loaded needle retraction feature. Stabilize the catheter, remove the pink wire slider, wire slider track and guidewire and appropriately dispose Apply the dressing, remove the porous flow plug and connect the IV set using the luer adapter.	response. Advance catheter into the vein while maintaining needle position. Activate the spring-loaded needle retraction feature. Stabilize the catheter, apply the dressing and connect the IV set using the luer adapter.	removal of componentry associated with the pink wire slider, wire slider track and guidewire. **Comment #1**
Materials of Construction	**Barrel (Housing):** Polycarbonate **Grip:** Polycarbonate **Needle Hub:** Polycarbonate **Needle**: Stainless Steel **Needle Tip Shield:** N/A **Spring**: Stainless Steel **Catheter Tubing:** Polyurethane w/ radiopaque barium sulfate **Adhesive:** Loctite **Catheter Hub:** Polycarbonate	**Barrel (Housing):** Polycarbonate **Grip:** Polycarbonate **Needle Hub:** Polycarbonate **Needle**: Stainless Steel **Needle Tip Shield:** N/A **Spring**: Stainless Steel **Catheter Tubing:** Polyurethane w/ radiopaque barium sulfate **Adhesive:** Loctite **Catheter Hub:** Polycarbonate	**Different** Predicate, excluding componentry associated with the pink wire slider, wire slider track and guidewire the materials of construction of the Subject device are the same. The addition of the componentry associated with the pink wire slider, wire slider track and guidewire do not raise any different questions of safety or effectiveness, as appropriate bench and biocompatibility testing was executed

Attribute	Subject – OSPREY Midline Closed IV Catheter System (OspreyEDC)	Predicate – OSPREY Closed IV Catheter System (K231626)	Substantial Equivalence
	Pinch Clamp: Polypropylene **Extension Tubing:** Tygon® **Luer Adapter:** Polycarbonate **Porous Flow Plug:** Porous Polyethylene w/ Carboxymethyl Cellulose (CMC) **Wire Slider Track:** Polycarbonate **Wire Slider Cap:** Polycarbonate **Guidewire:** Stainless Steel **Lubricant:** Silicone	**Pinch Clamp:** Polypropylene **Extension Tubing:** Tygon® **Luer Adapter:** Polycarbonate **Porous Flow Plug:** Porous Polyethylene w/ Carboxymethyl Cellulose (CMC) **Wire Slider Track:** N/A **Wire Slider Cap:** N/A **Guidewire:** N/A **Lubricant:** N/A	
Design Characteristics	**Catheter-Needle Interface:** Catheter through the needle **Needle Tip:** Beveled **Catheter Tip:** Rounded Tip	**Catheter-Needle Interface:** Catheter through the needle **Needle Tip:** Beveled **Catheter Tip:** Rounded Tip	**Different** Predicate, excluding componentry associated with the pink wire slider, wire slider track and guidewire the materials of construction of the Subject device are the same, and the difference in catheter OD/ID and length does not alter or raise different questions of safety and effectiveness. **Comment #2**
	Needle Retraction: Spring loaded retraction	**Needle Retraction:** Spring loaded retraction	
	IV Set Connection: Female Locking Luer Hub	**IV Set Connection:** Female Locking Luer Hub	
	Visualization: Flashback	**Visualization:** Flashback	
	Catheter OD: 0.0435 – 0.0445 in. **Catheter ID:** 0.0275 – 0.0325 in. **Catheter Length:** 3.25 in.	**Catheter OD:** 0.041 – 0.043 in. **Catheter ID:** 0.025 – 0.031 in. **Catheter Length:** 1.37 in.	
	Integrated Extension Tube:	**Integrated Extension Tube:**	

Attribute	Subject – OSPREY Midline Closed IV Catheter System (OspreyEDC)	Predicate – OSPREY Closed IV Catheter System (K231626)	Substantial Equivalence
	Incorporates an integrated extension tube, including a pinch clamp and female luer with porous (vent) plug.	Incorporates an integrated extension tube, including a pinch clamp and female luer with porous (vent) plug.	
	Catheter Hub – Guidewire Slider/Track Interface Guidewire track to support and stabilize guidewire slider; guidewire slide advances guidewire and catheter (catheter hub)	**Catheter Hub – Guidewire Slider/Track Interface** N/A	
	Power Injector: The OSPREY Midline Closed IV Catheter System (OspreyEDC) is suitable for use with power injectors rated for a maximum of 325 psi when connected to male luer lock.	**Power Injector:** The OSPREY Closed IV Catheter System (OspreyV2) is suitable for use with power injectors rated for a maximum of 325 psi when connected to male luer lock.	
Performance	Flashback Chamber / Technology: Yes <u>Sharps Prevention Feature:</u> Yes <u>Radiopaque:</u> Yes	Flashback Chamber / Technology: Yes <u>Sharps Prevention Feature:</u> Yes <u>Radiopaque:</u> Yes	**Identical**

Attribute	Subject – OSPREY Midline Closed IV Catheter System (OspreyEDC)	Predicate – OSPREY Closed IV Catheter System (K231626)	Substantial Equivalence
	Flow Rate: 30 mL/min	Flow Rate: 30 mL/min	**Identical**
Biocompatibility	Tested per ISO 10993-1: **PASS**	Tested per ISO 10993-1: **PASS**	**Identical**
Sterilization	EtO Sterilized	EtO Sterilized	**Identical**
Packaging	Sterile Barrier: Individual Tyvek and PET Pouches	Sterile Barrier: Individual Tyvek and PET Pouches	**Identical**
Shelf Life	6 - Months	6 - Months	**Identical**

Discussion of Differences in Technological Characteristics

Comment #1: The IFU of the Subject device is similar to that of the Predicate, as the OSPREY Midline Closed IV Catheter System (OspreyEDC) is also an intravascular catheter intended to be inserted into the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously, including its ability to be used with a power injector. The inclusion of additional instructions associated with the removal of the pink wire slider, wire slider track and guidewire componentry following the deployment of the Subject device's catheter does not raise additional concerns of safety and effectiveness.

Comment #2: The design characteristics of the Subject device and the Predicate remain the same, while the Subject device includes the addition of the componentry associated with the pink wire slider, wire slider track and guidewire their materials of construction are identical with those of the Predicate device and were subjected to appropriate biocompatibility testing based on ISO 10993-1:2018 for their respective contact type and duration which did not raise additional issues of safety and effectiveness.

Summary of Performance Data:

Bench tests were conducted to verify that the proposed device met all design specifications and to support substantial equivalence to the predicate device. Bench testing was performed on the subject device (OSPREY Midline Closed IV Catheter System (OspreyEDC)) in accordance with the standards below.

Performance

- ISO 10555-1:2013 + A1:2017 Sterile, single-use intravascular catheters - Part 1: General requirements
- ISO 10555-5:2013 Intravascular catheters – Sterile and single-use catheters Part 5: Over-needle Peripheral catheters
- ISO 80369-7:2021; Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications.
- ISO 80369-20:2015; Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods.
- ISO 8536-8:2015; Infusion equipment for medical use – Part 8: Infusion sets for single use with pressure infusion apparatus.
- ISO 7864:2016; Sterile hypodermic needles for single use — Requirements and test methods.
- ISO 9626:2016; Stainless steel needle tubing for the manufacture of medical devices.
- ISO 8536-4:2019; Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed.
- USP <788>; Particulate Matter for Injections (Method 1 Light Obscuration Particle Count Test).
- ISO 23908:2011 Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 11070:2014 + A1:2018; Sterile single-use intravascular introducers, dilators and guidewires

Biocompatibility

A biocompatibility evaluation, in accordance with 1) ISO 10993-1:2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing and 2) FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued Sept. 4, 2020), was conducted. The following testing was undertaken to support the outcome of the Subject device biocompatibility evaluation categorization externally communicating, both blood path indirect and circulating blood:

- ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016 Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Sterilization and Packaging validation

- ISO 14937:2009 Sterilization of health care products-General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical device
- AAMI TIR56:2013 Guidance for the development, validation and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4332-14: Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169-16: Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1886-16: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F2096-11 (2019): Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88-15: Standard Test Method for Seal Strength of Flexible Barrier Materials

Conclusion:

The differences between the predicate device to the subject device do not raise any new or different questions of safety or effectiveness. The subject OSPREY Midline Closed IV Catheter System (OsperyEDC) device is substantially equivalent to the Predicate OSPREY Closed IV Catheter System (OspreyV2) with respect to indications for use and technological characteristics.