April 14, 2023

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

Re: K223018
Trade/Device Name: OSPREY PERIPHERAL IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: March 10, 2023
Received: March 14, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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.
Acting 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K223018

Device Name

OSPREY PERIPHERAL IV Catheter System

Indications for Use *(Describe)*

OSPREY PERIPHERAL IV catheter 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.

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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K223018 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: April 14, 2023

Name of Device: OSPREY PERIPHERAL IV Catheter System

Common or Usual Name: Short-Term Less Than 30 Days Therapeutic, Intravascular Catheter

Classification Name: Intravascular Catheter

Regulatory Class: Class II

Product Code / Regulation: FOZ / 21 CFR § 880.5200

Predicate Device(s): K952861 Angiocath & Insyte Autoguard Catheters – Becton Dickinson Vascular Access inc.

Indications for Use:

OSPREY PERIPHERAL IV catheter 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.

Device Description:

The OPREY IV Catheter System 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. The device has a usable length catheter of 1.67 inches in a 20 Gauge size for short-term (<30 days) use.

Technological Characteristics:

The OSPREY PERIPHERAL IV Catheter's 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 through the access needle via its female tapered luer hub until it is fully engaged. The female tapered luer hub and proximal end of the device housing becomes an integrated locking female luer interface that then simultaneously activates the passive needle retraction of the access needle within the device housing. Since the catheter is deployed through the access needle, the OSPREY PERIPHERAL IV catheter tip design is optimized to facilitate off-axis delivery of infusate.

Comparison to Predicate:

The OSPREY PERIPHERAL IV Catheter is similar to the predicate device, BD Angiocath & Insyte™ Autoguard™ Catheters, with the minor differences: 1) material of construction, 2) catheter location/tip geometry, 3) needle retraction deployment, 4) flow rate, are detailed within the Notes following the Substantial Equivalence Table. Both devices have the following characteristics in common: 1) both are short term catheters, 2) both are radiopaque catheters, 3) both are peripheral catheters, 4) both are disposable, single use catheters, 5) both provide a shielding mechanism for the used needle.

Table VII - I: Subject / Predicate Device Comparison of Intended Use, Materials and Technological Characteristics

Attribute	Subject – OSPREY PERIPHERAL IV Catheter System	Predicate - BD Angiocath & Insyte™ Autoguard™ Catheters (K952861)	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 PERIPHERAL IV catheter 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.	An intravascular catheter is intended to be inserted into the patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids intravenously.	Identical
Critical Procedural Steps	Remove the device from the packaging and inspect before use. Insert needle into the target vein and observe blood flashback 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.	Remove the device from the packaging and inspect before use. Insert needle into the target vein and observe blood flashback 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.	Identical
Materials of Construction	**Barrel (Housing):** Polycarbonate	**Barrel:** Polycarbonate	

Attribute	Subject – OSPREY PERIPHERAL IV Catheter System	Predicate - BD Angiocath & Insyte™ Autoguard™ Catheters (K952861)	Substantial Equivalence
	Grip: Polycarbonate **Needle Hub:** Polycarbonate **Needle**: Stainless Steel **Spring**: Stainless Steel **Catheter Tubing:** Polyurethane w/ radiopaque barium sulfate **Adhesive:** Loctite **Catheter Hub:** Polycarbonate	**Grip:** Polycarbonate **Needle Hub:** Polycarbonate **Needle:** Stainless Steel **Spring:** Stainless Steel **Catheter Tubing:** Polyurethane w/ radiopaque barium sulfate **Adhesive:** Unknown **Catheter Adapter:** Polypropylene **Lubricants:** Silicone **Safety Activation Button:** Polycarbonate **Porous Flow Plug:** Porous Polyethylene w/ Carboxymethyl Cellulose (CMC) **Catheter Wedge:** Stainless Steel	Different Materials are well known; bench and biocompatibility testing demonstrate no different questions of safety or effectiveness were raised. Differences are discussed in **Note 1**
Design Characteristics	**Catheter-Needle Interface:** Catheter through the needle **Needle Tip:** Beveled **Catheter Tip:** Rounded Tip	**Catheter-Needle Interface:** Catheter over the needle **Needle Tip:** Beveled **Catheter Tip:** Tapered Tip	Different Both the subject device and the predicate device utilize a needle and catheter tube to deliver fluids directly into the vessel. The differences in the tip shape and interface do not alter or raise different questions of safety and effectiveness. Differences are discussed in **Note 2**

Attribute	Subject – OSPREY PERIPHERAL IV Catheter System	Predicate - BD Angiocath & Insyte™ Autoguard™ Catheters (K952861)	Substantial Equivalence
	Needle Retraction: Spring loaded retraction	**Needle Retraction:** Spring loaded retraction	Different Both the subject device and the predicate device utilize a spring-loaded needle retraction mechanism to permanently retract the needle into the catheter housing. The differences in activation method do not alter or raise different questions of safety and effectiveness. Differences are discussed in **Note 3**
	IV Set Connection: Female Locking Luer Hub	**IV Set Connection:** Female Locking Luer Hub	Identical
	Visualization: Flashback	**Visualization:** Flashback	Identical
	Catheter OD: 0.041 – 0.043 in. **Catheter ID:** 0.025 – 0.031 in. **Catheter Length:** 1.67 in.	**Catheter OD:** 0.041 – 0.044 in. **Catheter ID:** 0.030 – 0.033 in. **Catheter Length:** 1.88 in.	Different The differences in dimensions do not alter or raise different questions of safety and effectiveness, as the associated OD is appropriate for a 20GA catheter per ISO 10555-5.
Performance	Flashback Chamber / Technology: Yes Sharps Prevention Feature: Yes Radiopaque: Yes	Flashback Chamber / Technology: Yes Sharps Prevention Feature: Yes Radiopaque: Yes	Identical

Attribute	Subject – OSPREY PERIPHERAL IV Catheter System	Predicate - BD Angiocath & Insyte™ Autoguard™ Catheters (K952861)	Substantial Equivalence
	Flow Rate: 30 mL/min	Flow Rate: 54 mL/min	Different Both the subject device and the predicate device provide clinically acceptable flow rates to deliver fluids to the vessel. The different flow rates do not alter or raise different questions of safety and effectiveness. Differences are discussed in **Note 4**
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

Note 1 – The additional materials of construction for the referenced Predicate (BD Angiocath & Insyte™ Autoguard™ Catheters - K952861) are not required to ensure the safety and efficacy of the Subject (OSPREY PERIPHERAL IV Catheter System), specifically the Predicate devices Needle Stick Safety Feature is an active design requiring an activation button, while the Subject devices Needle Stick Safety Feature is passive and therefore doesn't require the additional component. These differences do not raise new or different questions of safety or effectiveness.

Note 2 – While the Predicate device incorporates the traditional over-the-needle PIV design that must enter the vessel with not only the tip of the needle, but also requires further advancement to allow for the catheter (mounted over-the-needle) to enter the vessel. Concerning the Subject device, the insertion process requires the clinician to only enter the vessel with the tip of the needle to deploy the catheter, as it resides within the needle and therefore will already reside within the vessel. Since the Subject devices catheter is deployed through the access needle it allows for the rounded tip to be designed with a directional flow feature with an angled skive, which cannot be achieved with the Predicate devices over-the-needle tapered catheter, as is needs to pass through the skin and vessel wall. These differences do not raise new or different questions of safety or effectiveness.

Note 3 – The Subject device has been designed with passive needle retraction technology activated upon fully advancing the catheter, while the Predicate device design is active, requiring an additional step by the Clinician of pushing the activation button. These differences do not raise new or different questions of safety or effectiveness, as both the Subject and Predicate devices are designed for the needle to be stored inside

their respective barrel (housing) when the safety function is activated to prevent accidental needlestick injuries. Performance testing per ISO 23908:2011 demonstrated that the safety mechanism feature performs as intended.

Note 4 – Though the stated flow rate of the Subject device is less than that of the Predicate, it is adequate to support its referenced Indications for Use, as the flow rate is significantly greater than the operating parameters of clinically prescribed flow rates for both gravity infusion and legally marketed volumetric pumps. The Subject device flow rate of 30 mL/min equates to 1800 mL/hr which is substantially greater than the maximum programable flow rate for legally marketed volumetric pumps (999 mL/hr). Therefore, these differences do not raise new or different questions of safety or 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 PERIPHERAL IV Catheter System) 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 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.

Biocompatibility

Subject device classified as: Externally communicating, Circulation blood path, Prolonged contact (> 24 hours to 30 days)

A biocompatibility evaluation, in accordance with 1) ISO 10993-1:2018, Biological Evaluationof 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 biocompatibility of the subject devices:

- 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
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- 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
- USP-NF <151> Pyrogen Test

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 and the subject device do not raise any new or different questions of safety or effectiveness. The OSPREY PERIPHERAL IV Catheter System is substantially equivalent to the BD Angiocath & Insyte Autoguard Catheters with respect to indications for use and technological characteristics.

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