August 31, 2023

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

Re: K231626
Trade/Device Name: OSPREY Closed IV Catheter System (OspreyV2)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: May 31, 2023
Received: June 2, 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,

Porsche Bennett
For 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231626

Device Name
OSPREY Closed IV Catheter System (OspreyV2)

Indications for Use *(Describe)*
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.

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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K231626 - 510(k) SUMMARY

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: August 31, 2023

Name of Device: OSPREY Closed IV Catheter System (OspreyV2)

Common or Usual Name: Intravascular Catheter

Classification Name: Intravascular Catheter

Regulatory Class: Class II

Product Code / Regulation: FOZ / 21 CFR § 880.5200

Predicate Device(s): Primary Predicate (A) **–** K223018 (OSPREY PERIPHERAL IV Catheter System) – SkyDance Vascular, Inc.

Class II, Intravascular Catheter, FOZ / 21 CFR § 880.5200

Secondary Predicate (B) – K102520 (Nexiva Closed IV Catheter System) – Becton Dickinson Vascular Access Inc.

Class II, Intravascular Catheter, FOZ / 21 CFR § 880.5200

Indications for Use

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.

Device Description

The OPREY Closed IV Catheter System (OspreyV2) 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. The device is placed in a thermal formed tray that goes into a Tyvek pouch providing the sterile barrier.

Principles of Operation

The OSPREY Closed IV Catheter System (OspreyV2) 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 the pink catheter hub having an integrated extension tube, including an incorporated pinch clamp, female luer with porous (vent) plug. Upon fully advancing the catheter hub within the proximal end of the device housing it simultaneously activates the passive needle retraction of the access needle within the device housing. Since the catheter is deployed through the access needle, the OspreyV2 catheter tip design is optimized to facilitate off-axis delivery of infusate. Additionally, the OspreyV2 is suitable for use with power injectors when connected to male luer lock.

Technological Characteristic Comparison to Predicate

The OSPREY Closed IV Catheter System (OpsreyV2) is similar to the predicate devices, OSPREY PERIPHERAL IV Catheter System and Nexiva Closed IV Catheter System. 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. Additionally, the OSPREY Closed IV Catheter System (OpsreyV2) incorporates an integrated extension tube, including a pinch clamp, and female luer with porous (vent) plug, as well as the ability to use with a power injector, consistent with the Nexiva Closed IV Catheter System.

Table I: Comparison Table of Subject Device to Both the Primary Predicate (A) and Secondary Predicate (B) Devices

Attribute	Subject – OSPREY Closed IV Catheter System (OspreyV2)	Primary Predicate (A) – OSPREY PERIPHERAL IV Catheter System (K223018)	Secondary Predicate (B) – BD Nexiva Closed IV Catheter System (K102520)	Substantial Equivalence
Classification	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	21 CFR §880.5200 Class II FOZ - Intravascular Catheter	**Identical**
Indications for Use	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.	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.	The Nexiva™ intravascular catheter is inserted into a patient's vascular system for a short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature and luer access port, aid in the prevention of needle-stick injuries. 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 18-22 gauge Nexiva™ catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.	**Similar** Primary Predicate: Subject device IFU is expanded to include its suitability for use with power injectors and any patient population based on vascular anatomy and appropriateness of procedure. Secondary Predicate: Subject device IFU is consistent with its suitability for use with power injectors and any patient population based on vascular anatomy and appropriateness of procedure. **Comment #1**
Critical Procedural Steps	Remove the device from the packaging and inspect before use.	Remove the device from the packaging and inspect before use.	Remove the device from the packaging and inspect before use.	**Identical**

Attribute	Subject – OSPREY Closed IV Catheter System (OspreyV2)	Primary Predicate (A) – OSPREY PERIPHERAL IV Catheter System (K223018)	Secondary Predicate (B) – BD Nexiva Closed IV Catheter System (K102520)	Substantial Equivalence
	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, remove the porous flow plug and connect the IV set using the luer adapter.	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.	Insert needle into the target vein and observe blood flashback response. Advance catheter into the vein while maintaining needle position. Withdrawal of needle activates needle tip safety feature. Stabilize the catheter, apply the dressing, remove the porous flow plug and connect the IV set using the luer adapter.	
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	**Barrel (Housing):** N/A **Grip:** Polycarbonate **Needle Hub:** Polycarbonate **Needle**: Stainless Steel **Needle Tip Shield:** Polycarbonate **Spring**: N/A **Catheter Tubing:** Polyurethane w/ radiopaque barium sulfate **Adhesive:** Unknown **Catheter Adapter:** Copolyester	**Similar** Primary Predicate: Excluding componentry associated with integrated extension tubing, the materials of construction of the Subject device are the same. The additional components of the subject device were tested for biocompatibility in accordance with ISO10993-1. Therefore, the addition of the componentry

Attribute	Subject – OSPREY Closed IV Catheter System (OspreyV2)	Primary Predicate (A) – OSPREY PERIPHERAL IV Catheter System (K223018)	Secondary Predicate (B) – BD Nexiva Closed IV Catheter System (K102520)	Substantial Equivalence
	Catheter Wing Adapter: N/A **Pinch Clamp:** Polypropylene **Extension Tubing:** Tygon® **Luer Adapter:** Polycarbonate **Porous Flow Plug:** Porous Polyethylene w/ Carboxymethyl Cellulose (CMC) **Lubricants:** N/A **Safety Activation Button:** N/A	**Catheter Wing Adapter:** N/A **Pinch Clamp:** N/A **Extension Tubing:** N/A **Luer Adapter:** Polycarbonate **Porous Flow Plug:** N/A **Lubricants:** N/A **Safety Activation Button:** N/A	**Catheter Wing Adapter:** TPE (Thermoplastic Elastomer) **Pinch Clamp:** Acetal **Extension Tubing:** Polyurethane **Luer Adapter:** Copolyester **Porous Flow Plug:** Porous Polyethylene w/ Carboxymethyl Cellulose (CMC) **Lubricants:** Unknown **Safety Activation Button:** N/A	associated with the integrated extension tubing does not raise new or different questions of safety and effectiveness. Secondary Predicate: The subject device was tested for biocompatibility in accordance with ISO10993-1. Therefore, the differences in component materials do not raise new or different questions of safety and effectiveness.
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	**Catheter-Needle Interface:** Catheter over the needle **Needle Tip:** Beveled **Catheter Tip:** Tapered Tip	**Similar Comment #2**
	Needle Retraction: Spring loaded retraction	**Needle Retraction:** Spring loaded retraction	**Needle Retraction:** N/A	
	IV Set Connection: Female Locking Luer Hub	**IV Set Connection:** Female Locking Luer Hub	**IV Set Connection:** Female Locking Luer Hub (Single Port Configuration)	
	Visualization: Flashback	**Visualization:** Flashback	**Visualization:** Flashback	
	Catheter OD: 0.041 – 0.043 in. **Catheter ID:** 0.025 – 0.031 in. **Catheter Length:** 1.37 in.	**Catheter OD:** 0.041 – 0.043 in. **Catheter ID:** 0.025 – 0.031 in. **Catheter Length:** 1.67 in.	**Catheter OD:** 0.042 – 0.045 in. **Catheter ID:** 0.031 – 0.034 in. **Catheter Length:** 1.25 in.	

Attribute	Subject – OSPREY Closed IV Catheter System (OspreyV2)	Primary Predicate (A) – OSPREY PERIPHERAL IV Catheter System (K223018)	Secondary Predicate (B) – BD Nexiva Closed IV Catheter System (K102520)	Substantial Equivalence
	Integrated Extension Tube: Incorporates an integrated extension tube, including a pinch clamp and female luer with porous (vent) plug.	**Integrated Extension Tube:** N/A	**Integrated Extension Tube:** Incorporates an integrated extension tube, including a pinch clamp and female luer with porous (vent) plug.	
	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.	**Power Injector:** N/A	**Power Injector:** The 18-22 gauge Nexiva™ catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.	
Performance	Flashback Chamber / Technology: Yes Sharps Prevention Feature: Yes Radiopaque: Yes	Flashback Chamber / Technology: Yes Sharps Prevention Feature: Yes Radiopaque: Yes	Flashback Chamber / Technology: Yes Sharps Prevention Feature: Yes Radiopaque: Yes	**Identical**
	Flow Rate: 30 mL/min	Flow Rate: 30 mL/min	Flow Rate: 58 mL/min	**Similar** Both the subject device and the Primary Predicate device have the same flow rate to deliver fluids to the vessel. Performance testing of the subject device demonstrates the difference in flow rate between the

Attribute	Subject – OSPREY Closed IV Catheter System (OspreyV2)	Primary Predicate (A) – OSPREY PERIPHERAL IV Catheter System (K223018)	Secondary Predicate (B) – BD Nexiva Closed IV Catheter System (K102520)	Substantial Equivalence
				subject and secondary predicate devices do not raise new or different questions of safety and effectiveness.
Biocompatibility	Tested per ISO 10993-1: **PASS**	Tested per ISO 10993-1: **PASS**	Tested per ISO 10993-1: **PASS**	**Identical**
Sterilization	EtO Sterilized	EtO Sterilized	EtO Sterilized	**Identical**
Packaging	Sterile Barrier: Individual Tyvek and PET Pouches	Sterile Barrier: Individual Tyvek and PET Pouches	Sterile Barrier: Thermal Formed Tray w/ Tyvek Lid	**Identical**
Shelf Life	6 - Months	6 - Months	Unknown	**Similar** Primary Predicate, has the same shelf life. Secondary Predicate: The subject device performance was tested over the proposed self-life and therefore the potential difference does not raise new or different questions of safety and effectiveness.

Discussion of Differences in Technological Characteristics

Comment #1: The IFU of the Subject device is similar to that of the Primary Predicate, as the OSPREY Closed IV Catheter System (OspreyV2) 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. It is different based on its ability to be used with power injectors and the inclusion of an integrated extension tube. The subject device performance testing demonstrates that the difference in intended use does not raise new or different questions of safety and effectiveness.

The subject device is similar in comparison to the Secondary Predicate as the IFU includes a needle-shielding feature which aids in the prevention of needle-stick injuries. Blood is contained within the devices during the catheter insertion process aiding in the prevention of blood exposure. The catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. Additionally, both the Subject and Secondary Predicate devices are suitable for use with power injectors. When considering the devices use (Subject and both the Primary & Secondary Predicate), the appropriateness of the patient's vascular anatomy must be taken into consideration. The Subjects devices IFU do not raise new or different questions of safety and effectiveness.

Comment #2: The subject and primary predicate devices are similar with the differences being the catheter length and integrated extension tubing. The subject device performance and biocompatibility testing demonstrates that the differences between the subject and primary predicate device do not raise new or different questions of safety and effectiveness. All other components are the same.

The subject device performance was tested in accordance with the bench testing listed below, particularly ISO 23908: 2011, ISO 10555-1: 2013, ISO 10555-5:2013, and ISO 8536-4:2019. Therefore, the difference in the needle retraction feature, the maximum power injection rate, and catheter dimensions do not raise new or different questions of safety and effectiveness.

Summary of Performance Data:

Bench tests were conducted to verify that the subject device met all design specifications and to support substantial equivalence to the predicate devices. Bench testing was performed on the subject device (OSPREY Closed IV Catheter System (OspreyV2)) 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

Biocompatibility

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

- 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

Clinical Testing:

No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

Conclusion:

The differences between the subject device and both the primary predicate and secondary predicate devices do not raise new or different questions of safety and effectiveness. The subject device, OSPREY Closed IV Catheter System (OsperyV2) device is substantially equivalent to both the Primary Predicate (A) OSPREY PERIPHERAL IV Catheter System and the Secondary Predicate (B) Nexiva™ Closed IV Catheter System, with respect to indications for use and technological characteristics.