July 6, 2022

Biotronik, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs and New Product Development
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K214038
Trade/Device Name: Oscar Peripheral Multifunctional Catheter system
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 23, 2022
Received: June 24, 2022

Dear Jon Brumbaugh:

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,

for

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K214038

Device Name
Oscar Peripheral Multifunctional Catheter system

Indications for Use *(Describe)*
The Oscar Peripheral Multifunctional Catheter system is indicated for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into and to dilate stenoses in femoral, popliteal and infrapopliteal arteries.

The product is also intended for injection of radiopaque contrast media for the purpose of angiography.

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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OSCAR PERIPHERAL MULTIFUNCTIONAL CATHETER SYSTEM (K214038)

TRADITIONAL 510(K) SUMMARY

Date Prepared:	July 5, 2022
Contact:	Jon Brumbaugh Vice President, Regulatory Affairs & New Product Development BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035 USA Phone (888) 345-0374 Fax (800) 913-6993 Email: jon.brumbaugh@biotronik.com
Trade Name:	Oscar Peripheral Multifunctional Catheter system
Generic/Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal
Classification & Panel:	Class II / 21 CFR § 870.1250, Cardiovascular
Product Code:	LIT
Predicate Device:	INFINITY Angioplasty Balloon Catheter (K192399, cleared May 20, 2020)
Reference Device	CXI Triforce Peripheral Crossing Set (K170931, cleared November 13, 2017)

Device Description

The Oscar Peripheral Multifunctional Catheter system is an intravascular balloon catheter system, supplied with a retractable sheath (Oscar Support Catheter), a flexible catheter (Oscar Dilator) and a PTA balloon (Oscar PTA balloon), allowing a variable guide wire support and injection of fluids, and adjustable length inflatable balloon up to 180 mm.

The over the wire (OTW) catheter has a retractable sheath allowing the balloon to be inflated at various lengths as determined by the physician. The balloon lengths are graduated with evenly spaced radiopaque markers.

The Oscar Peripheral Multifunctional Catheter system is a 4F and 6F catheter system with a shaft working length of 60 cm or 120 cm, compatible with 0.014” (Oscar 4F) and 0.018” (Oscar 6F) guide wires.

The device uses a semi-compliant balloon with a size dependent rated burst pressure and an indicated clinical use range of 6 atm to 16 atm. The balloon expands to a set nominal diameter (2.0, 2.5, 3.0, 4.0, 5.0, 6.0 and 7.0 mm). If required, separate PTA balloon catheters in same size range are also available separately.

Indications for Use

The Oscar Peripheral Multifunctional Catheter system is indicated for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into and to dilate stenoses in femoral, popliteal and infrapopliteal arteries.

The product is also intended for injection of radiopaque contrast media for the purpose of angiography.

Comparison of Technological Characteristics with the Predicate Devices

The BIOTRONIK Oscar Peripheral Multifunctional Catheter system is substantially equivalent to the predicate for this submission, the INFINITY Angioplasty Balloon Catheter (K192399, cleared May 20, 2020). The indications for use are similar, with only minor differences. The Oscar Peripheral Multifunctional Catheter system and the predicate device have comparable safety and technological features as mentioned below.

The minor device differences do not introduce new issues of safety or effectiveness as demonstrated by the Oscar Peripheral Multifunctional Catheter system performance testing.

Comparison of Characteristics between Proposed and Predicate Device			
Description	**BIOTRONIK Oscar Peripheral Multifunctional Catheter system (Subject Device)**	**INFINITY Angioplasty Balloon Catheter™ (Predicate Device)**	**Rationale for Substantial Equivalence**
510(k) Number	TBD	K192399	N/A
Classification	Class II	Class II	Same
Product Code	LIT	LIT	Same
Regulation	21 CFR 870.1250	21 CFR 870.1250	Same

Comparison of Characteristics between Proposed and Predicate Device			
Description	**BIOTRONIK Oscar Peripheral Multifunctional Catheter system (Subject Device)**	**INFINITY Angioplasty Balloon Catheter™ (Predicate Device)**	**Rationale for Substantial Equivalence**
Indications for Use	The Oscar Peripheral Multifunctional Catheter system is indicated for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into and to dilate stenoses in femoral, popliteal and infrapopliteal arteries. The product is also intended for injection of radiopaque contrast media for the purpose of angiography.	The INFINITY Angioplasty Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary or cerebrovascular arteries.	Comparable
Principle of operation	Inflation of semi-compliant balloon for dilation	Inflation of semi-compliant balloon for dilation	Identical
Catheter Type	Over the wire	Over the wire	Identical
Coating	Hydrophobic	Hydrophilic	Comparable
Recommended guide wire	0.014”/0.018”	0.018”	Comparable
Balloon Material	Semi- compliant	‘Semi-compliant’	Identical
Balloon Diameter (mm)	2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0 and 7.0 mm	5.0	Comparable
Balloon Length (mm)	Length: 20-180 mm (Ø2.0-6.0) Length: 20-100 mm (Ø7.0)	Length: 40-250 mm. Variable Marker bands located at 100 mm, 200 mm, and 250 mm on balloon length	Comparable

Comparison of Characteristics between Proposed and Predicate Device			
Description	**BIOTRONIK Oscar Peripheral Multifunctional Catheter system (Subject Device)**	**INFINITY Angioplasty Balloon Catheter™ (Predicate Device)**	**Rationale for Substantial Equivalence**
Balloon Marker	Distal radiopaque balloon marker (1) and subsequently two radiopaque markers (2) at 60 mm distance each for the dimensions 2-6 mm, or two radiopaque markers at 50 mm distance for the 7 mm dimension of the Oscar PTA balloon.	Marker bands located at 100 mm, 200 mm, and 250 mm on balloon length	Comparable
Balloon Length Variability	Yes	Yes Balloon length controlled by outer sheath placement relative distal tip of the balloon.	Identical
Outer Sheath	Yes	Yes	Identical
Number of radiopaque marker bands	3 for diameters 2-6mm 2 for 7mm diameter	5 Proximal and distal ends of balloon, 100 mm and 200 mm balloon length, and distal tip of outer sheath	Comparable
Location markers	PTA Balloon radiopaque markers: • Ø2.0-6.0: three markers starting distally, each 60 mm apart • Ø7.0: two markers starting distally, 50 mm apart	Yes Markers designate location of the sheath relative to the catheter shaft	Comparable
Catheter Shaft Length (cm)	4F / 6F: 120 cm (long) 6F: 60 cm (short)	150	Comparable
Sterilization Method	EO	EO	Identical
Single use	Yes	Yes	Identical
Supplied Sterile	Yes	Yes	Identical

Performance Data

All necessary performance testing was conducted on the Oscar Peripheral Multifunctional Catheter System to ensure that the device conforms to the design specification and to support a determination of substantial equivalence to the predicate device. The non-clinical bench testing included:

- Design Verification
  - Balloon compliance
  - Balloon nominal diameter
  - Balloon length
  - Balloon Fatigue
  - Marker band visibility
  - Inflation and deflation time
  - Device tracking, delivery, and retrieval
  - Torque strength
  - Kink resistance
  - Joint strength testing
  - Rated burst pressure
- Design Validation
- Biocompatibility Testing

In addition, BIOTRONIK has performed sterilization, shelf life and packaging validations. The collective results of the non-clinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Oscar components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Oscar do not introduce new issues of safety or effectiveness when compared to the predicate device.

Conclusions

Based on the performance testing and the technological characteristics, it can be concluded that the Oscar Peripheral Multifunctional Catheter System meets its established performance for its intended use and is substantially equivalent to the predicate device.