July 11, 2024

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

Re: K241711
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, KRA
Dated: June 13, 2024
Received: June 14, 2024

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 (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.

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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.07.11 09:09:02 -04'00'

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

K241711

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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OSCAR PERIPHERAL MULTIFUNCTIONAL CATHETER SYSTEM (K241711)

510(K) SUMMARY

Date Prepared:	July 10, 2024
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 (Primary), KRA (Secondary)
Predicate Device:	Oscar Peripheral Multifunctional Catheter system (K214038, cleared July 6,2022)

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 Oscar Peripheral Multifunctional Catheter system (K214038, cleared July 6, 2022). The modified Oscar Peripheral Multifunctional Catheter system after stabilizing pressure membrane elimination and the predicate device have identical technological features and indications for use 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			
Device 510(k) Number	**Predicate Device K214038**	**Subject Device TBD**	**Rationale for Substantial Equivalence**
Classification	Class II		Identical
Product Code	LIT	LIT/KRA	Comparable
Regulation	21 CFR 870.1250		Identical
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.		Identical
Principle of operation	Inflation of semi-compliant balloon for dilation		Identical
Catheter Type	Over the wire		Identical
Coating	Hydrophobic		Identical
Recommended guide wire	0.014”/0.018”		Identical
Balloon Material	Semi- compliant		Identical
Balloon Diameter (mm)	2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0 and 7.0 mm		Identical

Comparison of Characteristics between Proposed and Predicate Device			
Device 510(k) Number	**Predicate Device K214038**	**Subject Device TBD**	**Rationale for Substantial Equivalence**
Balloon Length (mm)	Length: 20-180 mm (Ø2.0-6.0) Length: 20-100 mm (Ø7.0)		Identical
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.		Identical
Balloon Length Variability	Yes		Identical
Outer Sheath	Yes		Identical
Number of radiopaque marker bands	3 for diameters 2-6mm 2 for 7mm diameter		Identical
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		Identical
Catheter Shaft Length (cm)	4F / 6F: 120 cm (long) 6F: 60 cm (short)		Identical
Sterilization Method	EO		Identical
Single use	Yes		Identical
Supplied Sterile	Yes		Identical

Performance Data

The following performance data were provided in support of the substantial equivalence.

PTA Catheter:

- Removal Force Balloon Protector
- Lesion Crossing Profile
- Balloon Compliance
- Balloon Compliance Burst Pressure and Failure Mode
- Longitudinal Balloon Compliance

Support Catheter+ PTA Catheter:

- Longitudinal Balloon Compliance at NP and RBP in Combination with Slippage

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.