April 4, 2025

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

Re: K250706
Trade/Device Name: Passeo-35 Xeo Peripheral Dilatation Catheter; Passeo-18 Peripheral Dilatation Catheters; Passeo-14 Peripheral Dilatation Catheter; Oscar Peripheral Multifunctional Catheter System; Pantera Pro Percutaneous Transluminal Coronary Angioplasty Catheter; Pantera LEO Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulation Number: 21 CFR 870.1250, 21 CFR 870.5100
Regulation Name: Percutaneous Catheter, Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LIT, LOX
Dated: March 7, 2025
Received: March 10, 2025

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.

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,

ARIEL G. ASH-SHAKOOR -S

Digitally signed by ARIEL G. ASH-SHAKOOR -S
Date: 2025.04.03 15:13:43 -04'00'

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250706

Device Name
Passeo-35 Xeo Peripheral Dilatation Catheter

Indications for Use *(Describe)*
The Passeo-35 Xeo peripheral dilatation catheter is indicated to dilate stenosis in the iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Passeo-35 Xeo is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

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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.*

510(k) Number *(if known)*
K250706

Device Name
Passeo-18 peripheral dilatation catheters

Indications for Use *(Describe)*

The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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)

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# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250706

Device Name
Passeo-14 Peripheral Dilatation Catheter

Indications for Use *(Describe)*
Passeo-14 is indicated for balloon dilatation of the stenotic portion of a lower limb artery for the purpose of improving perfusion.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250706

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)

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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.*

510(k) Number *(if known)*
K250706

Device Name
Pantera LEO Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

Indications for Use *(Describe)*

The Pantera LEO is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and for post dilatation of coronary stents.

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)

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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.*

510(k) Number *(if known)*
K250706

Device Name
Pantera Pro Percutaneous Transluminal Coronary Angioplasty Catheter

Indications for Use *(Describe)*

The Pantera Pro is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Pantera Pro (balloon diameter 2.0 – 4.0 mm) is also indicated for post-delivery expansion of balloon expandable stents.

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)

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**Passeo®-35 Xeo Peripheral Dilatation Catheter (K250706)**

**510(K) Summary**

| | |
|---|---|
| Date Prepared: | April 2, 2025 |
| Contact: | Jon Brumbaugh<br>Vice President, Regulatory Affairs & New Product Development<br>BIOTRONIK, Inc.<br>6024 Jean Road<br>Lake Oswego, OR 97035 USA<br>Phone (888) 345-0374<br>Email: jon.brumbaugh@biotronik.com |
| Trade Names: | Passeo-35 Xeo Peripheral Dilatation Catheter |
| Regulation Description: | Percutaneous catheter |
| Device Type: | Catheter, angioplasty, peripheral, transluminal |
| Product Code: | LIT |
| Regulation Number | 870.1250 |
| Predicate Device: | Passeo-35 Xeo (K222065) |

**Device Description**

BIOTRONIK's Passeo 35 Xeo Catheter is an over-the-wire (OTW) balloon dilatation catheter, indicated for dilatation of stenotic segments in peripheral vessels. The Passeo 35 Xeo Catheter is a dual lumen design with both lumens contained within one tube. The smaller lumen is the balloon inflation/deflation lumen. The larger lumen permits the use of guide wires with a maximum diameter of 0.035" to facilitate advancement of the Passeo 35 Xeo Catheter towards and through the lesion(s) to be dilated.

**Indications for Use**

The Passeo-35 Xeo peripheral dilatation catheter is indicated to dilate stenosis in the iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Passeo-35 Xeo is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

**Comparison of Technological Characteristics with the Predicate Devices**

The modified devices are substantially equivalent to the predicate devices and 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 performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-35 Xeo Predicate Device (K222065)** | **Subject Devices** |
| Proprietary name | Passeo-35 Xeo | Identical |
| Common name | PTA catheter | Identical |
| Classification | Class II (21 CFR 870.1250) | Identical |
| Classification name | Catheter, angioplasty, peripheral, transluminal | Identical |
| Product code | LIT | Identical |
| Indications for Use | The Passeo-35 Xeo peripheral dilatation catheter is indicated to dilate stenosis in the iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.<br>Passeo-35 is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. | Identical |
| Contraindications | Passeo-35 Xeo is contraindicated for use in patients with:<br>•A lesion that cannot be reached or treated with the dilatation catheter.<br>• Large amounts of acute or sub-acute thrombus at the target lesion.<br>•Perforated vessels.<br>•A lesion that lies within or adjacent to an aneurysm.<br>•Uncorrected bleeding disorders.<br>•A renal insufficiency or an allergy to contrast media. Furthermore, all general PTA and procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply. | Identical |

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-35 Xeo Predicate Device (K222065)** | **Subject Devices** |
| Intended user | Physicians competent in PTA procedures | Identical |
| Method of placement | Standard percutaneous access to site over a guide wire, with fluoroscopic visualization | Identical |
| Sterilization / Shelf Life / Packaging | 3 years | Identical |
| Sterilization | EO gas | Identical |
| Sterilization System | SteriMed EO Sterilizer<br>or<br>Sterichem EO Sterilizer | Identical |
| SAL | $10^{-6}$ | Identical |
| Shelf life | 3 years | Identical |
| Device description | Over the wire 2-lumen balloon catheter | Identical |
| Radiopaque markers | 2 markers– one at each end of the balloon<br>Material: 90% Pt / 10% Ir | Identical |
| Usable length [cm] | 90, 130, and 170 | Identical |
| Introducer sheath compatibility | 5F (Balloon Ø: 3 – 7 mm)<br>6F (Balloon Ø: 8 – 10 mm)<br>7F (Balloon Ø: 12 mm) *<br><br>*Size only available for Xeo with Catheter length 90, and 130 cm | Identical |
| Crossing profile | Ø: 3–7mm: max. 0.074 inches<br>Ø: 8–10mm: max. 0.083 inches | Identical |
| Guide wire compatibility | 0.035” | Identical |
| Shaft outer diameter [F] | 5 | Identical |

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-35 Xeo Predicate Device (K222065)** | **Subject Devices** |
| Balloon diameter [mm] | 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 12.0 | Identical |
| Balloon length [mm] | 20, 40, 60, 80, 100, 120, 150, 170, 200 and 250 | Identical |
| Balloon wrapping | 3-5 folds | Identical |
| Balloon Nominal pressure [atm] | 7 | Identical |
| Balloon RBP [atm] | 21 (Balloon Ø: 3mm)<br>18 (Balloon Ø: 4mm)<br>16 (Balloon Ø: 5 – 6 mm)<br>14 (Balloon Ø: 7 – 8 mm)<br>12 (Balloon Ø: 9mm)<br>11 (Balloon Ø: 10 mm)<br>10 (Balloon Ø: 12 mm) | Identical |
| Luer connectors and manifolds | Manifold (sub-component 1) with 1x female Luer lock connector with lugs (L2) – variant A<br><br>Manifold (sub-component 2) with 1x female Luer lock connector with lugs (L2) – variant A | Components will be brought into compliance with ISO 80369-7:2021 |

**Performance Data**

All necessary performance testing was conducted on the Passeo-35 Xeo Catheters to ensure that the devices conform to the design specification and to support a determination of substantial equivalence to the predicate devices.

The collective results of the performed testing demonstrated that the materials chosen, the manufacturing processes, and design of the components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does 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 Passeo-35 Xeo catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.

**Passeo-18 Peripheral Dilatation Catheters (K250706)**

**510(K) Summary**

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| | |
|---|---|
| Date Prepared: | April 2, 2025 |
| Contact: | Jon Brumbaugh<br>Vice President, Regulatory Affairs & New Product Development<br>BIOTRONIK, Inc.<br>6024 Jean Road<br>Lake Oswego, OR 97035 USA<br>Phone (888) 345-0374<br>Email: jon.brumbaugh@biotronik.com |
| Trade Names: | Passeo-18 peripheral dilatation catheters |
| Regulation Description: | Percutaneous catheter |
| Device Type: | Catheter, angioplasty, peripheral, transluminal |
| Product Code: | LIT |
| Regulation Number | 870.1250 |
| Predicate Device: | Passeo-18 (K151744) |

**Device Description**

The Passeo-18 peripheral dilatation catheter is intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae. The dilatation balloon is designed to inflate to a known diameter at a specific inflation pressure consistent with the compliance chart on the label. One radiopaque marker is located at each end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon catheter towards and across the lesion.

The dilatation catheter includes a soft tapered tip to facilitate advancement of the catheter. The dilatation catheter has two Luer-ports at the proximal end. One port (inflation port) serves for connecting an inflation device to inflate/deflate the balloon. The other port enables flushing of the guide wire lumen. The dilatation catheter has a hydrophobic silicone coating on the shaft outer surface and a hydrophobic patchwork coating on the balloon.

**Indications for Use**

The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

**Comparison of Technological Characteristics with the Predicate Devices**

The modified devices are substantially equivalent to the predicate devices and 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 performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-18 Predicate Device (K151744)** | **Subject Devices** |
| Proprietary name | Passeo-18 | Identical |
| Common name | PTA catheter | Identical |
| Classification | Class II (21 CFR 870.1250) | Identical |
| Classification name | Catheter, angioplasty, peripheral, transluminal | Identical |
| Product code | LIT | Identical |
| Indications for Use | The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. | Identical |
| Contraindications | Contraindications for this device and peripheral dilation catheters in general are:<br>Inability to cross the target lesion with a guide wire<br>Bleeding diathesis | Identical |

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-18 Predicate Device (K151744)** | **Subject Devices** |
| Intended user | Physicians competent in PTA procedures | Identical |
| Method of placement | Standard percutaneous access to site over a guide wire, with fluoroscopic visualization | Identical |
| Sterilization / Shelf Life / Packaging | 3 years | Identical |
| Sterilization | EO gas | Identical |
| Sterilization System | Sauter EO Sterilizer<br>or<br>Sterichem EO Sterilizer | Identical |
| SAL | $10^{-6}$ | Identical |
| Shelf life | 3 years | Identical |
| Device description | Over the wire balloon catheter | Identical |
| Radiopaque markers | 2 markers – one at each end of the balloon<br>Material: 90% Pt / 10% Ir<br>Length: 1.5 mm | Identical |
| Usable length [cm] | 90, 130, 150 (for balloon diameter 2.0 mm only) | Identical |
| Introducer sheath compatibility | 4F:<br>Balloon Ø: 2.0–5.0 mm; nominal length: all balloon lengths;<br>Ø: 6 mm, nominal length: 20 to 80 mm; Ø: 7 mm, nominal length: 20 to 60 mm<br>5F:<br>Balloon Ø: 6 mm, nominal length: 120 to 220 mm<br>Balloon Ø: 7 mm, nominal length: 80 to 220 mm | Identical |

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-18 Predicate Device (K151744)** | **Subject Devices** |
| Crossing profile | Ø: 2.0–5.0 mm: max. 0.057 inches<br>Ø: 6.0 mm: max. 0.061 inches<br>Ø: 7.0 mm: max. 0.071 inches | Identical |
| Guide wire compatibility | 0.018” | Identical |
| Shaft outer diameter [F] | 4 and 5 | Identical |
| Balloon diameter [mm] | 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0 | Identical |
| Balloon length [mm] | 20, 40, 60, 80, 120, 150, 170, 200, 220 | Identical |
| Balloon wrapping | 5 folds | Identical |
| Balloon Nominal pressure [atm] | 6 | Identical |
| Balloon RBP [atm] | 12 (Balloon Ø: 7-6 mm, 5x150 mm)<br>13 (Ø4-5 x 170-220 mm)<br>14 (Ø2-3.5 x 200-220 mm)<br>15 (Ø 2-3.4 x 20-170 mm, Ø 4 x 20-150 mm, Ø 5 x 20-120 mm) | Identical |
| Luer connectors and manifolds | Manifold with 2x female Luer lock connectors (L2) | Components will be brought into compliance with ISO 80369-7:2021 |

**Performance Data**

All necessary performance testing was conducted on the Passeo-18 Catheters to ensure that the devices conform to the design specification and to support a determination of substantial equivalence to the predicate devices.

The collective results of the performed testing demonstrated that the materials chosen, the manufacturing processes, and design of the components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does 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 Passeo-18 catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.

**Passeo-14 Peripheral Dilatation Catheter (K250706)**

**510(K) Summary**

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| | |
|---|---|
| Date Prepared: | April 2, 2025 |
| Contact: | Jon Brumbaugh<br>Vice President, Regulatory Affairs & New Product Development<br>BIOTRONIK, Inc.<br>6024 Jean Road<br>Lake Oswego, OR 97035 USA<br>Phone (888) 345-0374<br>Email: jon.brumbaugh@biotronik.com |
| Trade Names: | Passeo-14 Peripheral Dilatation Catheter |
| Regulation Description: | Percutaneous catheter |
| Device Type: | Catheter, angioplasty, peripheral, transluminal |
| Product Code: | LIT |
| Regulation Numbers | 870.1250 |
| Predicate Device: | Passeo-14 (K152240) |

**Device Description**

The Passeo-14 peripheral dilatation catheter is intended for the dilatation of stenotic segments in lower limb arteries. The dilatation balloon is designed to inflate to a known diameter at a specific inflation pressure consistent with the compliance chart on the label. One radiopaque marker is located at each end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon catheter towards and across the lesion.

The dilatation catheter includes a soft tapered tip to facilitate advancement of the catheter. The dilatation catheter has two Luer-ports at the proximal end. One port (inflation port) serves for connecting an inflation device to inflate/deflate the balloon. The other port enables flushing of the guide wire lumen.

**Indications for Use**

Passeo-14 is indicated for balloon dilatation of the stenotic portion of a lower limb artery for the purpose of improving perfusion.

**Comparison of Technological Characteristics with the Predicate Devices**

The modified devices are substantially equivalent to the predicate devices and 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 performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-14 Predicate Device (K152240)** | **Subject Devices** |
| Proprietary name | Passeo-14 | Identical |
| Common name | PTA catheter | Identical |
| Classification | Class II (21 CFR 870.1250) | Identical |
| Classification name | Catheter, angioplasty, peripheral, transluminal | Identical |
| Product code | LIT | Identical |
| Indications for Use | The Passeo-14 is indicated for balloon dilatation of the stenotic portion of a lower limb artery for the purpose of improving perfusion. | Identical |
| Contraindications | All general contraindications for percutaneous transluminal angioplasty (PTA) are contraindications for this device. Contraindications for this device and peripheral dilatation catheters in general are:<br>• Lesions that cannot be reached or treated with the system<br>• Large amounts of acute or subacute thrombus at the target lesion<br>• Perforated vessels<br>• Lesion that lies within or adjacent to an aneurysm<br>• Uncorrected bleeding disorders<br>• Renal insufficiency or an allergy to contrast media<br>Furthermore, all procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply. | Identical |

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-14 Predicate Device (K152240)** | **Subject Devices** |
| Intended user | Physicians competent in PTA procedures | Identical |
| Method of placement | Standard percutaneous access to site over a guide wire, with fluoroscopic visualization | Identical |
| Sterilization / Shelf Life / Packaging | 3 years | Identical |
| Sterilization | EO | Identical |
| Sterilization System | Sauter EO Sterilizer<br>or<br>Sterichem EO Sterilizer | Identical |
| SAL | $10^{-6}$ | Identical |
| Shelf life | 3 years | Identical |
| Device description | Over the wire 2-lumen balloon catheter | Identical |
| Radiopaque markers | 2 markers – one at each end of the balloon<br>Material: 90% Pt / 10% Ir<br>Length: 1.0 mm | Identical |
| Usable length [cm] | 90, 120, 150 | Identical |
| Introducer sheath compatibility | 4F for all balloon diameters | Identical |
| Crossing profile | Ø: 1.5mm: max. 1.12mm (0.044 in)<br>Ø: 2.0mm: max. 1.14mm ().045 in)<br>Ø: 2.5mm: max. 1.19mm (0.047 in)<br>Ø: 3.0mm: max. 1.24mm (0.049 in)<br>Ø: 3.5 4 mm: max 1.32mm (0.052 in) | Identical |
| Guide wire compatibility | 0.014” | Identical |

| Table 1: Comparison of Passeo Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Passeo-14 Predicate Device (K152240)** | **Subject Devices** |
| Shaft outer diameter [F] | Max. 3.9 (proximal)<br>Max. 3.1 F (distal) | Identical |
| Balloon diameter [mm] | 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 | Identical |
| Balloon length [mm] | 20, 40, 70, 100, 140, 180, 220 | Identical |
| Balloon wrapping | 3 folds | Identical |
| Balloon Nominal pressure [atm] | 7 | Identical |
| Balloon RBP [atm] | 14 for all diameters | Identical |
| Luer connectors and manifolds | Manifold with 2x female Luer lock connectors (L2) | Components will be brought into compliance with ISO 80369-7:2021 |

**Performance Data**

All necessary performance testing was conducted on the Passeo-14 Catheters to ensure that the devices conform to the design specification and to support a determination of substantial equivalence to the predicate devices.

The collective results of the performed testing demonstrated that the materials chosen, the manufacturing processes, and design of the components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does 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 Passeo-14 catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.

**OSCAR® PERIPHERAL MULTIFUNCTIONAL CATHETER SYSTEM (K250706)**

**510(K) Summary**

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| | |
|---|---|
| Date Prepared: | April 2, 2025 |
| Contact: | Jon Brumbaugh<br>Vice President, Regulatory Affairs & New Product Development<br>BIOTRONIK, Inc.<br>6024 Jean Road<br>Lake Oswego, OR 97035 USA<br>Phone (888) 345-0374<br>Email: jon.brumbaugh@biotronik.com |
| Trade Names: | Oscar Peripheral Multifunctional Catheter system |
| Regulation Description: | Percutaneous catheter |
| Device Type: | Catheter, angioplasty, peripheral, transluminal |
| Product Code: | LIT (Primary), KRA (Secondary) |
| Regulation Number | 870.1250, 870.1210 |
| Predicate Device: | Oscar (K241711) |

**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 modified devices are substantially equivalent to the predicate devices and 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 performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

| Table 1: Comparison Oscar Peripheral Multifunctional Catheter System Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Oscar Peripheral Multifunctional Catheter system Predicate Device (K241711)** | **Subject Devices** |
| Proprietary Name | Oscar Peripheral Multifunctional Catheter system | Identical |
| Classification | Class II (21 CFR 870.1250) | Identical |
| Product Code | LIT/KRA | Identical |
| 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. | 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.<br>The product is also intended for injection of radiopaque contrast media for the purpose of angiography. | 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 |
| Balloon Adjustable Length (mm) (BL) | Length: 20-180 mm (Ø2.0-6.0)<br>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 |

| Table 1: Comparison Oscar Peripheral Multifunctional Catheter System Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Oscar Peripheral Multifunctional Catheter system Predicate Device (K241711)** | **Subject Devices** |
| Balloon Length Variability | Yes | Identical |
| Outer Sheath | Yes | Identical |
| Number of Radiopaque Marker Bands | 3 for diameters 2-6mm<br>2 for 7mm diameter | Identical |
| Location Markers | PTA Balloon radiopaque markers:<br>• Ø2.0-6.0: three markers starting distally, each 60 mm apart<br>• Ø7.0: two markers starting distally, 50 mm apart | Identical |
| Support Catheter Usable Length (SCUL) | 4F / 6F: 108 cm (long)<br>6F: 60 cm (short) | Identical |
| Total Length (TL) | 4F / 6F: 141 cm / 142 cm (long)<br>6F: 93 cm / 86 cm (short) | Identical |
| Maximum Usable Catheter Length (UL) | 4F / 6F: 127 cm / 128 cm (long)<br>6F: 80 cm / 72 cm (short) | Identical |
| Sterilization Method | EO | Identical |
| SAL | $10^{-6}$ | Identical |
| Shelf Life | 3 years | Identical |
| Luer connectors and manifolds | 4F: Manifold (Balloon) with 2x female Luer lock connectors (L2), Connector (Dilator) with 1x female Luer lock connector (L2)<br><br>6F: Manifold (Balloon) with 2x female Luer lock connectors (L2), Connector (Dilator) with 1x female Luer lock connectors (L2) | Components will be brought into compliance with ISO 80369-7:2021 |

**Performance Data**

All necessary performance testing was conducted on the Oscar Catheters to ensure that the devices conform to the design specification and to support a determination of substantial equivalence to the predicate devices.

The collective results of the performed testing demonstrated that the materials chosen, the manufacturing processes, and design of the components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does 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 catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.

**Pantera LEO Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter (K250706)**
**510(K) Summary**

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|---|---|
| Date Prepared: | April 2, 2025 |
| Contact: | Jon Brumbaugh<br>Vice President, Regulatory Affairs & New Product Development<br>BIOTRONIK, Inc.<br>6024 Jean Road<br>Lake Oswego, OR 97035 USA<br>Phone (888) 345-0374<br>Email: jon.brumbaugh@biotronik.com |
| Trade Names: | Pantera LEO Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter |
| Regulation Description: | Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter |
| Device Type: | Catheter, transluminal coronary angioplasty, percutaneous |
| Product Code: | LOX |
| Regulation Number | 870.5100 |
| Predicate Device: | Pantera LEO (K242969) |

**Device Description**

Pantera LEO is a PTCA rapid exchange system with a balloon at the distal end of the catheter. A Luer port at the proximal end enables the attachment of an inflation device for the inflation of the balloon. The catheter provides a lumen, which enables the use of a guide wire to position the catheter. Radiopaque balloon markers aid in the placement of the catheter's balloon segment under fluoroscopy.

**Indications for Use**

The Pantera LEO is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and for post dilatation of coronary stents.

**Comparison of Technological Characteristics with the Predicate Devices**

The modified devices are substantially equivalent to the predicate devices and 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 performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

| Table 1: Comparison of Pantera LEO Subject Device to Predicate Device | | |
|---|---|---|
| **Characteristic** | **Pantera LEO Predicate Device (K242969)** | **Subject Devices** |
| Proprietary name | Panera LEO Fast-Exchange PTCA Catheter | Identical |
| Common name | PTCA Catheter | Identical |
| Classification | PTCA Catheter, LOX, Class II (21 CFR 870.5100) | Identical |
| Product code | LOX | Identical |
| Indications for Use | The Pantera LEO is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and for post dilatation of coronary stents. | Identical |
| Contraindications | All general contraindications for percutaneous transluminal coronary angioplasty (PTCA) are contraindications for this device.<br>Contraindications for this device and for PTCA in general are:<br>- Lesions that cannot be reached or treated with the system.<br>- Target vessel unprotected left main coronary artery.<br>- Coronary artery spasm in the absence of a significant stenosis.<br>Furthermore, all procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply. | Identical |
| Intended user | Physicians competent in PTCA procedures | Identical |
| Method of placement / principles of operation | Device operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end | Identical |
| Sterilization | EO gas | Identical |
| SAL | $10^{-6}$ | Identical |
| Shelf life | 3 years | Identical |
| Device description | Device is a PTCA rapid exchange system with a balloon at the distal end of the catheter. | Identical |
| Balloon diameter [mm] | 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0, 4.5, 5.0 | Identical |
| Balloon length [mm] | 8, 12, 15, 20, 30 | Identical |

| Table 1: Comparison of Pantera LEO Subject Device to Predicate Device | | |
|---|---|---|
| **Characteristic** | **Pantera LEO Predicate Device (K242969)** | **Subject Devices** |
| Radiopaque markers | Ø all sizes: Two marker bands | Identical |
| Usable length [cm] | 145 | Identical |
| Guiding catheter compatibility<br>(Min. guiding catheter I.D) | Single Device: 5F (0.056 inch/1.42 mm) | Identical |
| Guide wire compatibility | 0.014 inch (0.36 mm) | Identical |
| Balloon Nominal pressure [atm] | all sizes: 14 atm | Identical |
| Balloon RBP [atm] | Ø: 2.0-4.0 mm: 20 atm<br>Ø: 4.5–5.0 mm: 18 atm | Identical |
| Distal outer shaft coating | Hydrophilic coating | Identical |
| Balloon coating | all sizes: Hydrophobic coating | Identical |
| Balloon folding | Ø 2.0 – 5.0 mm: Tri-fold | Identical |
| Luer connectors and manifolds | Hub with one female Luer lock connector (L2) | Components will be brought into compliance with ISO 80369-7:2021 |

**Performance Data**

All necessary performance testing was conducted on the Pantera LEO Catheters to ensure that the devices conform to the design specification and to support a determination of substantial equivalence to the predicate devices.

The collective results of the performed testing demonstrated that the materials chosen, the manufacturing processes, and design of the components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does 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 Pantera LEO catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.

**Pantera Pro Percutaneous Transluminal Coronary Angioplasty Catheter (K250706)**

**510(K) Summary**

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|---|---|
| Date Prepared: | April 2, 2025 |
| Contact: | Jon Brumbaugh<br>Vice President, Regulatory Affairs & New Product Development<br>BIOTRONIK, Inc.<br>6024 Jean Road<br>Lake Oswego, OR 97035 USA<br>Phone (888) 345-0374<br>Email: jon.brumbaugh@biotronik.com |
| Trade Names: | Pantera Pro Percutaneous Transluminal Coronary Angioplasty Catheter |
| Regulation Description: | Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter |
| Device Type: | Catheter, transluminal coronary angioplasty, percutaneous |
| Product Code: | LOX |
| Regulation Number | 870.5100 |
| Predicate Device: | Pantera Pro (K242969) |

**Device Description**

Pantera Pro is a PTCA rapid exchange system with a balloon at the distal end of the catheter. A Luer port at the proximal end enables the attachment of an inflation device for the inflation of the balloon. The catheter provides a lumen, which enables the use of a guide wire to position the catheter. Radiopaque balloon markers aid in the placement of the catheter's balloon segment under fluoroscopy.

**Indications for Use**

The Pantera Pro is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Pantera Pro (balloon diameter 2.0 – 4.0 mm) is also indicated for post-delivery expansion of balloon expandable stents.

**Comparison of Technological Characteristics with the Predicate Devices**

The modified devices are substantially equivalent to the predicate devices and 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 performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

| Table 1: Comparison of Pantera Pro Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Pantera Pro Predicate Device (K242969)** | **Subject Devices** |
| Proprietary name | Pantera Pro Coronary Dilatation Catheter | Identical |
| Common name | PTCA Catheter | Identical |
| Classification | PTCA Catheter, LOX, Class II (21 CFR 870.5100) | Identical |
| Product code | LOX | Identical |
| Indications for Use | The Pantera Pro is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Pantera Pro (balloon diameter 2.0 – 4.0 mm) is also indicated for post-delivery expansion of balloon expandable stents. | Identical |
| Contraindications | All general contraindications for percutaneous transluminal coronary angioplasty (PTCA) are contraindications for this device.<br>Contraindications for this device and for PTCA in general are:<br>- Lesions that cannot be reached or treated with the system.<br>- Target vessel unprotected left main coronary artery.<br>- Coronary artery spasm in the absence of a significant stenosis.<br>Furthermore, all procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply. | Identical |
| Intended user | Physicians competent in PTCA procedures | Identical |
| Method of placement / principles of operation | Device operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end | Identical |
| Sterilization | EO gas | Identical |
| SAL | $10^{-6}$ | Identical |
| Shelf life | 3 years | Identical |
| Device description | Device is a PTCA rapid exchange system with a balloon at the distal end of the catheter. | Identical |

| Table 1: Comparison of Pantera Pro Subject Devices to Predicate Devices | | |
|---|---|---|
| **Characteristic** | **Pantera Pro Predicate Device (K242969)** | **Subject Devices** |
| Balloon diameter [mm] | 1.25, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 | Identical |
| Balloon length [mm] | 6, 10, 15, 20, 25, 30 | Identical |
| Radiopaque markers | Ø1.25 - 1.5 mm: One marker band<br>Ø >1.5 mm: Two marker bands | Identical |
| Usable length [cm] | 140 | Identical |
| Guiding catheter compatibility (Min. guiding catheter I.D) | Single Device: 5F (0.056 inch/1.42 mm) | Identical |
| Guide wire compatibility | 0.014 inch (0.36 mm) | Identical |
| Balloon Nominal pressure [atm] | all sizes: 7 atm | Identical |
| Balloon RBP [atm] | all sizes: 14 atm | Identical |
| Distal outer shaft coating | Hydrophilic coating | Identical |
| Balloon coating | Ø 1.25 – 2.0 mm: Hydrophilic coating<br>Ø 2.5 - 4.0 mm: Hydrophobic coating | Identical |
| Balloon folding | Ø 1.25 – 1.5 mm: Two-fold<br>Ø 2.0 – 4.0 mm: Tri-fold | Identical |
| Luer connectors and manifolds | Hub with one female Luer lock connector (L2) | Components will be brought into compliance with ISO 80369-7:2021 |

**Performance Data**

All necessary performance testing was conducted on the Pantera Pro Catheters to ensure that the devices conform to the design specification and to support a determination of substantial equivalence to the predicate devices.

The collective results of the performed testing demonstrated that the materials chosen, the manufacturing processes, and design of the components meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does 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 Pantera Pro catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.