February 16, 2023

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

Re: K222065
Trade/Device Name: Passeo-35 Xeo Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: January 9, 2023
Received: January 10, 2023

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.02.16 08:51:08 -05'00'

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)*
K222065

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 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.

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510(K) SUMMARY: BIOTRONIK PASSEO-35 XEO PERIPHERAL DILATATION CATHETER (K222065)

Date Prepared:	January 6, 2023
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:	Passeo-35 Xeo Peripheral Dilatation Catheter
Generic/Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal
Classification & Panel:	Class II / 21 CFR § 870.1220, Cardiovascular
Product Code:	LIT
Predicate Device:	BIOTRONIK Passeo-35 Percutaneous Transluminal Angioplasty (PTA)Catheter (K142379, cleared December 5, 2014)

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, popliteral and infrapopliteral arteries and for the treatment of obstructive lesions of native and 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 BIOTRONIK Passeo-35 Xeo Peripheral Dilatation Catheter is substantially equivalent to the predicate device BIOTRONIK Passeo-35 Percutaneous Transluminal Angioplasty (PTA)Catheter (K142379, cleared December 5, 2014). The indications for use are similar,

with only minor differences. The Passeo-35 Xeo and the predicate device have substantially equivalent safety and technological features as mentioned below.

The minor device design differences do not introduce new issues of safety or effectiveness as demonstrated by the Passeo-35 Xeo Peripheral Dilatation Catheter performance testing.

Comparison of Passeo-35 Xeo to Predicate Device Passeo-35			
Characteristic	**Predicate Device**	**Subject Device**	**Comparison**
Proprietary name	Passeo-35 (K142379)	Passeo-35 Xeo (K222065)	New Name
Common name	PTA catheter		Unchanged
Classification	Class II (21 CFR 870.1250)		Unchanged
Classification name	Catheter, angioplasty, peripheral, transluminal		Unchanged
Product code	LIT		Unchanged
Intended use	The Passeo-35 peripheral dilatation catheter is intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae for the purpose of improving perfusion.	The Passeo-35 Xeo peripheral dilatation catheter is intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae for the purpose of improving perfusion.	Updated to reflect device name
Indications for Use	The Passeo-35 peripheral dilatation catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infra (popliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	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 is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.	Comparable
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: • Lesions that cannot be reached or treated with the system • Large amounts of acute or subacute thrombus at the target lesion • Perforated vessels • Lesion that lies within or adjacent to an aneurysm • Uncorrected bleeding disorders • Renal insufficiency or an allergy to contrast media Furthermore, all procedure-related contraindications as	Passeo-35 Xeo is contraindicated for use in patients with: •A lesion that cannot be reached or treated with the dilatation catheter. • Large amounts of acute or sub-acute thrombus at the target lesion. •Perforated vessels. •A lesion that lies within or adjacent to an aneurysm. •Uncorrected bleeding disorders. •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.	Comparable

Comparison of Passeo-35 Xeo to Predicate Device Passeo-35			
Characteristic	**Predicate Device**	**Subject Device**	**Comparison**
	described in the national and international guidelines of the respective medical associations apply.		
Intended user	Physicians competent in PTA procedures		Unchanged
Method of placement	Standard percutaneous access to site over a guide wire, with fluoroscopic visualization		Unchanged
Sterilization / Shelf Life / Packaging	3 years		Unchanged
Sterilization	EO gas		Unchanged
SAL	10^{-6}		Unchanged
Shelf life	3 years		Unchanged
Protective sheath	Balloon has a HDPE protective sheath. HDPE spiral dispenser sealed in a Tyvek® and PET/PE pouch. Product is packed in an outer cardboard carton.		Unchanged
Device description	Over the wire 2-lumen balloon catheter		Unchanged
Radiopaque markers	2 markers– one at each end of the balloon Material: 90% Pt / 10% Ir Length: 1.5 mm		Unchanged
Usable length [cm]	80, 90 and 130	90, 130, and 170	Comparable
Crossing profile	Ø: 3–7mm: max. 0.074 inches Ø: 8–10mm: max. 0.083 inches		Unchanged
Guide wire compatibility	0.035”		Unchanged
Shaft outer diameter [F]	5		Unchanged
Balloon diameter [mm]	3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0	3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 12.0	Comparable
Balloon length [mm]	20, 40, 60, 80, 100, 120, 150, 170, 200	20, 40, 60, 80, 100, 120, 150, 170, 200 and 250	Comparable
Balloon wrapping	5 folds	3-5 folds	Comparable
Balloon Nominal pressure [atm]	7		Unchanged
Balloon RBP [atm]	20 (Balloon Ø: 3mm) 18 (Balloon Ø: 4mm) 16 (Balloon Ø: 5 – 6 mm) 14 (Balloon Ø: 7 – 8 mm) 12 (Balloon Ø: 9mm) 11 (Balloon Ø: 10 mm)	21 (Balloon Ø: 3mm) 18 (Balloon Ø: 4mm) 16 (Balloon Ø: 5 – 6 mm) 14 (Balloon Ø: 7 – 8 mm) 12 (Balloon Ø: 9mm) 11 (Balloon Ø: 10 mm) 10 (Balloon Ø: 12 mm)	Comparable

Performance Data

All necessary performance testing was conducted on the BIOTRONIK Passeo-35 Xeo Peripheral Dilatation Catheter 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 Rated Burst Pressure
  - Balloon Rated Burst Pressure in Stent
  - Balloon Fatigue
  - Balloon Fatigue in Stent
  - Flexibility and Kink Test
  - Torque Strength
  - Compatibility to Accessories
  - Crossing Profile
  - Simulated Use
  - Tensile strength
  - Retraction Force
  - Trackability
  - Pushability
- 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 Passeo-35 Xeo Catheters meet the established specifications necessary for consistent performance during its intended use. The collective bench testing demonstrates that the Passeo-35 Xeo Catheters 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 BIOTRONIK Passeo-35 Xeo Peripheral Dilatation Catheter meets its established performance for its intended use and is substantially equivalent to the predicate device.