



Food and Drug Administration
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October 8, 2015

BIOTRONIK, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K151744

Trade/Device Name: Paseo-18 Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 4, 2015
Received: September 9, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K151744

Device Name
Passeo-18 peripheral dilatation catheter

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Passeo-18 Peripheral Dilatation Catheter Special 510(k) Premarket Notification

510(k) Summary

Name and Address of Sponsor: BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

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Date Prepared: June 24, 2015

Device Name:

Proprietary Name: Passeo-18
Common Name: Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification: Class II (21 CFR 870.1250)
Classification Name: Catheter, angioplasty, peripheral, transluminal
Product Code: LIT

Predicate Device:

	510(k) #	Device Name	Manufacturer	Date of Clearance
Predicate:	K072765	Passeo-18	BIOTRONIK	12-Dec-2007

General 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.

The dilatation catheter is compatible with guide wire and introducer sheath sizes according to the recommendations on the label.

Indication 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.

Sizes																												
Balloon Length (mm)		20			40			60			80			120			150			170			200			220		
Usable Length (cm)		90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150
Nominal Balloon Ø (mm)	2	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		
	2.5	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	3	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	3.5	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	4	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	5	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	6	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	7	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	

Purpose of Submission:

BIOTRONIK submits this 510(k) for clearance of additional device size configurations for the Passeo-18 including additional balloon lengths up to 220mm, referred to collectively as Passeo-18 LE. Additionally, a minor change affecting the entire product range that includes consolidation to a single balloon catheter design. Other changes previously documented as letters to file are also reported.

Summary of technological characteristics in comparison to Predicate Device:

Testing according to the existing design controls demonstrates that the Passeo-18 LE is comparable to the predicate device. The Passeo-18 catheters are identical to the predicate in terms of indications for use, intended use and principles of operation and fundamental technology. Modifications to technological characteristics do not raise new or different questions of safety and effectiveness.

Additional balloon lengths and balloon diameters have been added to the product line. Catheters will now be constructed using one, consolidated design instead of two separate design variants. Minor changes to the grade of materials for catheter construction and materials for packaging have been included. The substantial equivalence of these modifications are supported by product testing conducted according to the existing design controls.

Non-Clinical Performance Testing

Test Name	Test Conditions / Specifications	Summary Results
Dimensional Verification		
Visual and Dimensional Inspection	The balloon catheter was visually inspected for defects, printing, coating homogeneity, x-ray marker positioning and adherence to dimensional specs.	Inspectional acceptance criteria were met.
Crossing Profile (system profile)	The diameter of the device is measured by passing the device through a ring-hole gauge to verify French size compatibility.	Acceptance criteria for crossing profile were met. Crossing profile is within specs of predicate.
Simulated Use Testing		
Simulated Use	Testing is conducted to demonstrate that the balloon catheter can be safely and reliably prepared, delivered, and retracted using the recommended techniques and instructions for use, without damage to the device.	Acceptance criteria were met. Test shows device performs similar to predicate in a simulated use environment.

Test Name	Test Conditions / Specifications	Summary Results
Trackability and Pushability	Test recorded frictional force (N) when tracked over a guide wire in arterial model	Acceptance criteria were met. Test shows device performs similar to predicate in a simulated use environment.
Pullback and reintroduction test	With the balloon in an appropriate sheath, the friction to introduce and pullback the device after inflation to RBP is evaluated.	Pullback and reintroduction was comparable or better than comparator product. Device performs similar to predicate.
Balloon Inflation / Deflation Time	Inflation and deflation time are measured with the device placed in an anatomical model. Inflation and deflation times were measured for characterization.	Inflation time was characterized and deflation time was determined to be according to specifications within the instructions for use.
Compatibility with Contrast media	Devices were stored for in contrast medium (ionic and non-ionic) for a specified time, dilated to RBP and then visually inspected.	No visible damage or deformation. Device performs similar to predicate.
Mechanical Testing		
Balloon Compliance Radial	Radial compliance is calculated as the difference between balloon diameter at NP and at RBP.	Radial compliance meets acceptance criteria. Device performs similar to predicate
Balloon Compliance Axial	Axial compliance (balloon length at RBP and NP) of the device is measured to verify that it meets product specification.	The difference between balloon length at RBP and NP is within specification.
Balloon burst strength	This test determines the balloon Rated Burst Pressure (RBP). The balloon is inflated until burst and pressure at burst is recorded. The burst failure mode is recorded.	Balloons met acceptance criteria for lower 99.9% quantile at 95% confidence interval for all sizes.
Balloon Fatigue	The balloons were subjected to repeat inflation/deflation cycles to determine survivability of the balloon. Any loss of pressure, whether due to failure of the balloon, shaft or proximal or distal seals, was reported as a test failure. All failure modes were recorded.	Results demonstrate that 90% of the balloons will survive the test with at least 95% confidence.
Tensile Strength Catheter	Following simulated use, a tensile strain is applied along the relevant catheter region until the first sign of fracture. The force (Fmax) at first sign of damage is recorded.	Tensile strength performance (Fmax) for distal and proximal balloon sections met performance specifications.
Resistance to Kink	Test was performed to determine the minimum bending radius of the catheter shaft at proximal and distal locations	Measured mean catheter kink radius was well within the acceptance criteria.
Torsional rigidity	Test was performed to assess the ability to inflate and deflate the balloon following application of a torsional load.	Device meets acceptance criteria. Device performs similar to predicate.
Rotatability	Test was performed to evaluate torque response. The proximal end of the device is rotated until the first rotational movement at the distal end is observed.	Device meets acceptance criteria. Device performs similar to predicate.

Test Name	Test Conditions / Specifications	Summary Results
Post-Dilatation Test	In a simulated arterial model, balloon is positioned within a deployed stent and subjected to multiple inflation/deflation cycles.	All samples withstood all inflation/deflation cycles within the stent without bursting. Device performs similar to predicate.
Biocompatibility		
Cytotoxicity	L929 cells are incubated with test article extracts and evaluated for percentage of cell growth inhibition and compared to a control sample (control: cells exposed to extraction medium).	Growth analyses of cells cultured with test article extract showed no cytotoxic effects of the test article.
Gas Chromatography – Mass Spectrometry (GC/MS)	The old materials are compared to the new materials. The test articles are extracted in different solvents (polar and non-polar, e.g. purified water, isopropyl alcohol and hexane) and the extracts are analyzed by GC-MS fingerprint analysis.	There are no significant differences between old and new materials
Fourier Transform Infrared Spectroscopy (FT-IR) analysis	Fourier Transform Infrared Spectroscopy (FT-IR) was utilized to compare the chemical composition of the new materials and old materials. The resulting FT-IR spectra were compared.	Materials had greater than 99% correlation according to FT-IR analysis. The new materials are similar to the predicate.
Sterilization Validation		
Correction factor and bioburden	Test conducted to determine typical device bioburden prior to sterilization.	Determine bioburden correction factor. Device meets specifications for CFU/device.
Test for inhibitors and activators, Pyrogen test	Test conducted to determine device endotoxin levels after manufacturing.	Bacterial endotoxin test results met acceptance criteria.
Validation of the Sterilization Success	Test was performed according to determine if sterilization parameters are sufficient for a SAL of 1×10^{-6} .	Testing confirmed SAL of 10^{-6} . The device performs similar to predicate.
Residual gas analysis: EO and ECH	Test conducted to determine EO and ECH residuals on the device following two sterilization cycles.	Device meets acceptance criteria. The device performs similar to predicate.

Clinical Test Data

The determination of substantial equivalency on this subject device does not rely upon the clinical data. There is no clinical data submitted in this application.

Labeling

The instructions for use and labeling were updated with the relevant new device size information.

Conclusion

Based on the non-clinical performance testing using existing design controls from the predicate, the subject Passeo-18 catheter performs as well as the predicate and is therefore substantially equivalent to the predicate Passeo-18 catheter.