DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 26, 2017

Biotronik, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs And Compliance
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K163660
Trade/Device Name: Pantera LEO
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: December 22, 2016
Received: December 27, 2016

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. 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" (21 CFR 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163660

Device Name
Pantera LEO

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary per 21 CFR 807.92

Date Prepared:	January 25, 2017
Name and Address of Applicant:	BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035
510(k) Contact Person and Phone Number:	Jon Brumbaugh Vice President, Regulatory Affairs and Compliance Phone: (888) 345-0374 Fax: (503) 635-9936 jon.brumbaugh@biotronik.com
Proprietary Name:	Pantera LEO
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Device Classification:	Class II (special controls)
Regulation Number:	870.5100
Classification Name:	Catheter, transluminal coronary angioplasty, percutaneous
Product Code:	LOX
Predicate Device(s):	BIOTRONIK Pantera Pro (K160985, cleared October 7, 2016)
Device Description:	The Pantera LEO PTCA catheter is a sterile, single-use, intravascular balloon catheter for the dilatation of stenotic segments in coronary arteries or bypass grafts. The dilatation balloon is designed to inflate to a known diameter and length at a specific inflation pressure consistent with the compliance chart, which is included in the Instructions for Use (IFU), Compliance Data Card (CDC), and on the labels. The dilatation catheter has a soft tip that is tapered at the distal end of the catheter to facilitate advancement of the catheter. The balloon is folded to achieve a low crossing profile and is connected to the tip. A radiopaque marker is located at each end of the balloon cylindrical section to facilitate fluoroscopic visualization and positioning of the balloon catheter to and across the lesion. The proximal section of the catheter is a single lumen stainless steel hypotube with a single Luer port for the inflation / deflation of the balloon. The Pantera LEO has two coatings; a hydrophobic silicone coating on the outer surface of the hypotube (proximal outer shaft) and balloon, and a hydrophilic polymeric-based coating on the outer surface of the distal outer shaft. The dilatation catheter is compatible with guide wire and guiding catheter sizes according to the recommendations on the label.

Pantera LEO Available Sizes (Usable Catheter Length = 145 cm)					
Balloon Ø [mm]	**Balloon length [mm]**				
	8	**12**	**15**	**20**	**30**
2.0	X	X	X	X	X
2.25	X	X	X	X	X
2.5	X	X	X	X	X
2.75	X	X	X	X	X
3.0	X	X	X	X	X
3.25	X	X	X	X	X
3.5	X	X	X	X	X
3.75	X	X	X	X	X
4.0	X	X	X	X	X
4.5	X	X	X	X	X
5.0	X	X	X	X	X

X	Available sizes

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.

Purpose of Submission: BIOTRONIK submits this 510(k) for clearance of Pantera LEO Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter. The predicate device is the Pantera Pro PTCA Dilatation Catheter (K160985, cleared October 7, 2016). The modifications described in this submission are limited to the balloon compliance and materials of construction, which are utilized in other BIOTRONIK devices.

Comparison of Technological Characteristics Pantera LEO has the same intended use as the predicate device. The indications for use are similar, with only minor differences in the wording for post-dilatation. The fundamental scientific technology and principles of operation of the Pantera LEO are identical to the predicate device Pantera Pro. There are only minor technological differences between the Pantera LEO and the Pantera Pro, which can be summarized as differences in materials of construction of a few device components. However, these differences in material do not affect the principles of operation or intended use. The safety and effectiveness of Pantera LEO are supported by product testing conducted according to the BIOTRONIK design controls.

Summary of Non-Clinical Data

Testing according to BIOTRONIK design control and verification/validation processes demonstrates that the Pantera LEO is comparable to the predicate device. Modifications to technological characteristics do not raise new or different questions of safety and effectiveness.

Design Verification in-vitro testing:
The following in-vitro bench tests were completed on the Pantera LEO in accordance with the requirements of Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010, and verify that it meets the required performance specifications.

- Dimensional Verification
- Balloon Preparation, Deployment and Retraction
- Balloon Rated Burst Pressure
- Balloon Fatigue (Repeat Balloon Inflations)
- Balloon Compliance (Diameter vs. Pressure)
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Tip Pull Test
- Flexibility and Kink Test
- Torque Strength
- Radiopacity
- Coating Integrity
- Particulate Evaluation
- Shelf Life testing to support a 3-year shelf life

Additional Tests for Catheters Intended for In-Stent Restenosis or for Stent Expansion following Stent Deployment:

- Balloon Rated Burst Pressure in Stent
- Balloon Fatigue / Repeat Balloon Inflation in Stent

Biocompatibility Testing:
The Pantera LEO PTCA Catheter is intended for short-term use in direct contact with circulating blood. Therefore, it is classified in accordance with ISO 10993-1 “Biological evaluation of medical devices” as an external communicating device with limited (≤ 24 h) contact duration with circulating blood. Biocompatibility testing was conducted to demonstrate that the requirements of ISO 10993-1 and the 2016 FDA Guidance for ISO 10993 (#1811) have been met for the Pantera LEO PTCA balloon catheter. There was no evidence of adverse biological effects, indicating that there is no biological risk caused by the materials/device or possible leachable substances. Therefore, it can be concluded that the Pantera LEO balloon catheters are biologically safe for their intended use.

The Pantera LEO met all specified design and performance requirements. No new safety or effectiveness issues were raised during the testing. The bench validation testing and biocompatibility testing demonstrated that the Pantera LEO is substantially equivalent in terms of safety and effectiveness to the predicate device.

Summary of Clinical 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.

Conclusion:

The intended use of the subject device, Pantera LEO, as described in the labeling, is identical to that of the predicate device, Pantera Pro (K160985). In addition, the indications for use are similar, with only minor differences in the wording for post-dilatation, and the fundamental scientific technology has not changed. BIOTRONIK believes that the minor differences proposed in this submission do not raise new or different questions regarding safety and effectiveness and that substantial equivalence for safety and effectiveness can be determined using existing design controls. Summaries of performance testing, showing Pantera LEO performs equivalently or better than the predicate, have been provided in this Special 510(k). The biocompatibility testing shows the materials of construction are biologically safe for the intended use. Therefore, Pantera LEO should be considered substantially equivalent to the predicate device, Pantera Pro.