October 25, 2024

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

Re: K242969
Trade/Device Name: Pantera Pro; Pantera LEO
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: September 26, 2024
Received: September 26, 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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.10.25 15:22:32 -04'00'

Lydia Glaw
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.

Submission Number *(if known)*

K242969

Device Name

Pantera Pro; Pantera LEO

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.

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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K242969

Special 510(k) Premarket Notification

510(K) SUMMARY: Pantera Pro and Pantera LEO Catheters

Date Prepared:	October 23, 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 Names:	Pantera Pro and Pantera LEO
Generic/Common Names:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheter, transluminal coronary angioplasty, percutaneous
Product Code:	LOX
Predicate Device:	Pantera Pro (K160985) and Pantera LEO (K163660).

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.

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 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.

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 Predicate Devices

Description	Pantera Pro (K160985 – Predicate)	Pantera LEO (K163660 - Predicate)	Subject Devices Rationale for Substantial Equivalence
510(k) Number	K160985	K163660	K242969
Classification	Class II	Class II	Identical
Product Code	LOX	LOX	Identical
Regulation	21 CFR 870.5100	21 CFR 870.5100	Identical
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.	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.	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-	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

	delivery expansion of balloon expandable stents.		
Principle of Operation	Device operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end	Device operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end	Identical
Catheter Type	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter	Identical
Guiding catheter compatibility	Single Device: 5F (0.056 inch/1.42 mm)	Single Device: 5F (0.056 inch/1.42 mm)	Identical
Balloon Material	Polyamide 12	Polyamide 12	Identical
Balloon Diameter	1.25, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0	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	6, 10, 15, 20, 25, 30	8, 12, 15, 20, 30	Identical
Radiopaque Markers	Ø1.25 - 1.5 mm: One marker band Ø >1.5 mm: Two marker bands	Ø all sizes: Two marker bands	Identical
Usable Length	140	145	Identical
Guide wire compatibility	0.014 inch (0.36 mm)	0.014 inch (0.36 mm)	Identical
Balloon Nominal pressure [atm]	all sizes: 7 atm	all sizes: 14 atm	Identical
Balloon RBP [atm]	all sizes: 14 atm	Ø: 2.0-4.0 mm: 20 atm Ø: 4.5–5.0 mm: 18 atm	Identical
Distal outer shaft coating	Hydrophilic Coating Slip Coat Base Coat Type 90174 B Slip Coat Top Coat Type 90172 A	Hydrophilic Coating Slip Coat Base Coat Type 90174 B Slip Coat Top Coat Type 90172 A	Similar – alternative basecoat formulation. Top coat remains unchanged
Balloon coating	Ø 1.25 – 2.0 mm: Hydrophilic coating Ø 2.5 - 4.0 mm: Hydrophobic coating	all sizes: Hydrophobic coating	Identical
Sterilization Method	EO gas	EO Gas	Identical
Single Use	Single-Use	Single-Use	Identical
Supplied Sterile	Sterile	Sterile	Identical

Performance Data

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

- Product performance - coating integrity and particulates
- Biocompatibility
- Microbiological - Bioburden
- Shelf-Life - coating integrity and particulates

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 and Pantera LEO catheters meet their established performance for their intended use and are substantially equivalent to the predicate devices.