DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 29, 2016

BrosMed Medical Co., Ltd.
Mr. Stephen Lee
Deputy General Manager
15th Building, SMEs Venture Park
SongShan Lake Hi-Tech Development Zone
Dongguan, 523808 China

Re: K160256
Trade/Device Name: Polux, Minerva, and Atropos PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: July 05, 2016
Received: July 08, 2016

Dear Mr. Lee:

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 yours,

Brian D. Pullin -S

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)*
K160256

Device Name
Polux PTA Balloon Dilatation Catheter
Minerva PTA Balloon Dilatation Catheter
Atropos PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*

The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
This device is also indicated for stent dilatation post-deployment 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

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

Submitter:	BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park SongShan Lake Hi-Tech Industrial Development Zone Dongguan 523808, China Office: +86 (769) 2289 2018 Fax: +86 (769) 2289 2016
Contact Person:	Stephen Lee
Date Prepared	July 29, 2016
Trade Name:	Polux PTA Balloon Dilatation Catheter Minerva PTA Balloon Dilatation Catheter Atropos PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Dilatation Catheter
Classification Name:	Percutaneous catheter (21 CFR 870.1250, Product Code LIT)
Predicate Devices:	NanoCross Elite 0.014" Over-The-Wire PTA Balloon Dilatation Catheter (K141118; cleared July 18, 2014) Sterling Over-The-Wire (OTW) PTA Balloon Dilatation Catheter (K132430; cleared October 17, 2013) Mustang Balloon Dilatation Catheters (K103751; cleared March 22, 2011)
Device Description:	The Polux, Minerva, and Atropos PTA Balloon Dilatation Catheters are over-the-wire (OTW) peripheral balloon catheters designed for Percutaneous Transluminal Angioplasty (PTA). These three PTA balloon dilatation catheters have been bundled in one 510(k) submission due to the similar/equivalent construction and identical material of the products. As summarized by the comparison between the Polux, Minerva, and Atropos PTA Balloon Dilatation Catheters in Table 1, the devices only differ in guidewire compatibility, balloon diameter, and balloon length. The devices are offered with catheter working lengths of 70, 90 and 150 cm. The guidewire compatibility includes 0.014" for the Polux device, 0.018" for the Minerva device and 0.035" for the Atropos device. The balloon diameters range from 1.5 mm to 10.0 mm, with balloon working lengths ranging from 5 mm to 200 mm. The balloon material is made of a semi-compliant Pebax material and offered in diameters 1.5 mm to 10.0 mm with a rated burst pressure of 14 atmospheres. It is a coaxial double lumen catheter with a balloon located near the distal tip. One lumen is used for inflation of the balloon and accessed via the side leg port. The second lumen, starting at the straight entry port, allows access to the distal tip of the catheter for guide wire insertion. The balloon has radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. The balloon is dilated using the side leg port, at which the balloon material expands to a known diameter depending on the pressure delivered. The working pressure range for the balloon is between the nominal size pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

Intended Use:	The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent dilatation post-deployment in the peripheral vasculature
Technological Characteristics:	Comparing the subject devices against their corresponding predicates reveal similarities in technological characteristics including: indications for use, operating principle, guidewire compatibility, catheter design, sheath compatibility, sterilization method, sterility assurance level, and similar ranges of balloon diameters, balloon effective lengths, and catheter working lengths. The major differences between the subject and predicate devices include materials, smaller balloon lengths, and different balloon configurations.
Performance Data:	Both *in vitro* performance tests, such as dimensional verification, balloon preparation, deployment, and retraction, balloon rated burst pressure, balloon fatigue, balloon compliance, balloon inflation and deflation time, catheter bond strength, tip pull strength, flexibility and kinking, torque strength, radiopacity, coating integrity, particulate evaluation, balloon burst (in stents, balloon fatigue (in stent) and also biocompatibility tests, such as cytotoxicity, sensitization, hemocompatibility, pyrogenicity, acute systemic toxicity, intracutaneous reactivity and genotoxicity (bacterial mutagenicity and *in vitro* mouse lymphoma) were conducted on the PTA balloon catheter. The test results met all acceptance criteria, were similar to predicate devices, and ensure that the PTA balloon catheter design and construction are suitable for its intended use.
Conclusion:	This information supports the determination of substantial equivalence between the PTA balloon dilatation catheter and the predicate devices described above.

Table 1: Comparison of Technical Characteristics between the Subject Devices (BrosMed Polux, Minerva, and Atropos PTA Balloon Dilatation Catheters)

	Polux 0.014”	Minerva 0.018”	Atropos 0.035”	Difference	Control Method
Device	catheter, angioplasty, peripheral, transluminal	catheter, angioplasty, peripheral, transluminal	catheter, angioplasty, peripheral, transluminal	Identical	n/a
Regulation Description	Percutaneous catheter.	Percutaneous catheter.	Percutaneous catheter.	Identical	
Regulation Medical Specialty	Cardiovascular	Cardiovascular	Cardiovascular	Identical	
Review Panel	Cardiovascular	Cardiovascular	Cardiovascular	Identical	
Product Code	LIT	LIT	LIT	Identical	
Premarket Review	Office of Device Evaluation 6(ODE)	Office of Device Evaluation 6(ODE)	Office of Device Evaluation 6(ODE)	Identical	
	Division of Cardiovascular Devices (DCD)	Division of Cardiovascular Devices (DCD)	Division of Cardiovascular Devices (DCD)	Identical	
	Peripheral Interventional Devices Branch (PIDB)	Peripheral Interventional Devices Branch (PIDB)	Peripheral Interventional Devices Branch (PIDB)	Identical	
Submission Type	510(k)	510(k)	510(k)	Identical	
Regulation Number	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	Identical	
Device Class	2	2	2	Identical	
Intended Use	The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature	The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature	The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature	Identical	IFU
Balloon Characteristic	semi-compliant	semi-compliant	semi-compliant	Identical	Design Verification; labeling
Nominal Pressure (Nom)	6atm	6atm	6atm	Identical	Design Verification; labeling
Rated Burst Pressure (RBP)	14atm	14atm	14atm	Identical	Design Verification; labeling
Guide wire Compatibility	Max. 0.014"(0.36mm)	Max. 0.018" (0.46mm)	Max. 0.035"(0.89mm)	Different	Design Verification; labeling
Balloon Diameter	1.5-6.0mm	1.5-10.0mm	3.0-10.0mm	Different	Design Verification; labeling
Balloon Length	5-200mm	5-200mm	20-200mm	Different	Design Verification; labeling
Shaft Length	70,90,150	70,90,150	70,90,150	Identical	Design Verification; labeling