April 11, 2023

BrosMed Medical Co., Ltd.
Crystal Lee
Registration Affairs Manager
15th Building, SMEs Venture Park, SongShan Lake
Hi-Tech Industrial Development Zone
Dongguan, GD 523808
China

Re: K230705
Trade/Device Name: POT PTCA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (Ptca) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: March 14, 2023
Received: March 14, 2023

Dear Crystal 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. 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2023.04.11 10:18:58 -04'00'

For

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)*
K230705

Device Name
POT PTCA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The POT PTCA balloon dilatation catheter is indicated for:
·balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion
·balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction
·balloon dilatation of a stent after implantation (balloon models Ø2.25 mm - Ø5.00 mm only)
Note: Bench testing was conducted with the POT PTCA Balloon Dilatation Catheter and marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to difference in stent design.

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

1. GENERAL INFORMATION

1.1 Submitter

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Dongguan 523808, China
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1.2 Contract person

Crystal Lee,
Email: crystallee@brosmed.com
Office: +86 (769) 2289 2018

1.3 Date of Preparation

March 03, 2023

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

POT PTCA Balloon Dilatation Catheter

2.1.2 Common/Usual Name

Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

2.1.3 Classification Information

Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Classification Regulation:	21 CFR 870.5100
Device Class:	Class II (Special Controls)
Product Code:	LOX
Review Panel:	Cardiovascular

3. PREDICATE DEVICES

- Apollo Balloon Dilatation Catheter (K133852, cleared on Sep 19, 2014);
- Apollo Balloon Dilatation Catheter (K153742, cleared on Aug 08, 2016).

4. DESCRIPTION OF THE DEVICE

The POT PTCA balloon dilatation catheter is a sterile, flexible tube designed to be used in percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible Nylon balloon at its distal tip. It is typically a rapid exchange (Rx) type with a single-lumen catheter. It is a single-use device and available in various sizes for the dilatation of small, narrowed, or obstructed coronary arteries or bypass grafts.

5. INDICATION FOR USE

The indication for use / intended use statement for the Subject device is as follows:

The POT PTCA Balloon Dilatation Catheter is indicated for:

- balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;
- balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction;
- balloon dilatation of a stent after implantation (balloon models Ø2.25 mm - 5.00 mm only)

Note: Bench testing was conducted with the POT PTCA Balloon Dilatation Catheter and marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to difference in stent design.

6. SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison of the POT PTCA Balloon Dilatation Catheter and Apollo Balloon Dilatation Catheter cleared in K133852 and K153742 shows that the subject device incorporates substantial equivalence general design components, material and performance specifications, manufacturing processes, sterilization process, packaging materials and design, and the same indications for use and principles of operation as predicates.

Please see **Table 1** below for the comparison between Subject device and Predicate devices.

Table 3. Substantial Equivalence Comparison of Subject Device and Predicate Devices

Technological Characteristic	Subject Device POT	Predicate Device Apollo (K133852 & K153742)	Comparison
Indications for Use	The POT PTCA balloon dilatation catheter is indicated for: ·balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion ·balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction ·balloon dilatation of a stent after implantation (balloon models Ø2.25 mm - Ø5.00 mm only) Note: Bench testing was conducted with the POT PTCA Balloon Dilatation Catheter and marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to difference in stent design.	The Apollo balloon dilatation catheter is indicated for: ·balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion ·balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction ·balloon dilatation of a stent after implantation (balloon models Ø2.0 mm - Ø5.00 mm only) Note: Bench testing was conducted with the Apollo Balloon Dilatation Catheter and marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to difference in stent design.	Identical
Fundamental device design	Rx type sterilized PTCA catheter	Rx type sterilized PTCA catheter	Identical

Technological Characteristic	Subject Device POT	Predicate Device Apollo (K133852 & K153742)	Comparison
General catheter design	Tip, balloon, body tubing, hub, 2 radiopaque markers	Tip, balloon, body tubing, hub, 2 radiopaque markers	Identical
Compatible guidewire (in)	0.014	0.014	Identical
Catheter working length (cm)	140	140	Identical
Balloon diameter range (mm)	2.25-5.0	2.0-5.0	Equivalence
Balloon length range (mm)	6-15	6-30	Equivalence
Balloon cone length	Shorter	Longer	Equivalence
Nominal Pressure (atm)	14	14	Identical
Rated Burst Pressure (atm)	20-22	20-22	Identical

7. PERFORMANCE TESTING SUMMARY

Additional bench testing were performed to support a determination of substantial equivalence between subject device and predicates in accordance with the FDA guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "The Special 510(k) Program - Guidance for Industry and FDA Staff". The results of all tests provide reasonable assurance that the proposed POT PTCA catheter has been designed and tested to assure conformance to the requirements of its intended use.

All additional testing were conducted on the subject device as recommended in FDA PTCA guidance:

- Dimensional verification
- Simulated Use
- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Balloon Burst (in stent)
- Balloon Fatigue (in stent)

In vitro bench testing met all acceptance criteria and demonstrated that the subject device performed as intended and did not impact the functionality of the device.

8. CONCLUSION

The information presented in this special 510(k) submission demonstrates that the proposed modifications for the subject device do not raise new/different questions of safety and effectiveness as compared to the predicate device. Therefore, the POT PTCA Balloon Dilatation Catheter is substantially equivalent to the Apollo Balloon Dilatation Catheter cleared in K133852 and K153742.