October 22, 2024

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

Re: K241478
Trade/Device Name: Tri-Wedge PTA Scoring Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: May 23, 2024
Received: May 24, 2024

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 (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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.10.22 11:48:18 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241478

Device Name

Tri-Wedge PTA Scoring Balloon Dilatation Catheter

Indications for Use *(Describe)*

Tri-Wedge PTA Scoring Balloon Dilatation Catheter is indicated 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.

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.

510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter

BrosMed Medical Co., Ltd.
15th Buildings, SMEs Venture Park
SongShan Lake Hi-Tech Industrial Development Zone
Dongguan 523808, China
Office: +86 (769) 2289 2018
Fax: +86 (769) 2289 2016

1.2 Contract person

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

1.3 Date of Preparation

October 22, 2024

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name
Tri-Wedge PTA Scoring Balloon Dilatation Catheter

2.1.2 Submission 510(k) number
K241478

2.1.3 Common/Usual Name
Percutaneous Transluminal Angioplasty (PTA) Scoring Catheter

2.1.4 Classification Information

Classification Name:	Catheters, Peripheral, Cutting/Scoring
Classification Regulation:	21 CFR 870.1250
Device Class:	Class II (Special Controls)
Product Code:	PNO
Review Panel:	Cardiovascular

3. PREDICATE DEVICE AND REFERENCE DEVICES

- Primary Predicate Device: AngioSculpt PTA Scoring Balloon Catheter (K150634, cleared on May 31, 2016)
- Reference Device: UltraScore Focused Force PTA Balloon (K172571, cleared on September 22, 2017)

4. DESCRIPTION OF THE DEVICE

The Tri-Wedge PTA Scoring Balloon Dilatation Catheter is an over-the-wire (OTW) peripheral balloon dilatation catheter. The catheter working length is 50cm, 75cm, 90cm and 150cm. Balloon diameters range from 3.0mm to 8.0mm. The balloon is made of a minimally compliant material with rated burst pressure of 20atm for Ø3.0-6.0mm and 16atm for Ø7.0-8.0mm. A coaxial double lumen catheter for balloon inflation and guide wire insertion is bonded to a female luer connector to form the proximal shaft. The balloon and the coaxial double lumen are welded to compose the distal of the catheter. The catheter

surface is coated with hydrophilic coating from the tip to the distal shaft. A scoring element with three parallel struts wraps around the balloon. The balloon has radiopaque markers for positioning the balloon relative to the stenosis. The guide wire lumen is compatible with a standard 0.018-inch or 0.035-inch guide wire that enters from the tip of the catheter and extends out from the hub. The catheter is sterilized with EO and for single use only.

5. INDICATION FOR USE

The indication for use / intended use statement for the Tri-Wedge PTA Scoring Balloon Dilatation Catheter is as follows:

- The balloon dilatation catheter is indicated 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.

6. INTENDED USE COMPARISION SUMMARY

The subject device and the predicate devices, are intended to be used in identical interventional procedures within the same peripheral vasculature, serving the same fundamental purposes. Therefore, they can be considered substantially equivalent in terms of their intended use.

Element of Comparison	**Proposed device**	**Primary Predicate device**	**Reference device**
Product Name	Tri-Wedge	AngioSculpt	UltraScore
Product Code	PNO	PNO	PNO
Regulation Number	870.1250	870.1250	870.1250
Intended use	The Tri-Wedge PTA Scoring Balloon Dilatation Catheter is indicated 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.	The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.	The UltraScore Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self expanding stents, and stent grafts in the peripheral vasculature.

7. TECHNOLOGICAL CHARACTERISTICS COMPARISION SUMMARY

The Subject device and Predicate devices are similar in terms of general design components, material and performance specifications. Please see below table for the technology comparison between Subject device and Predicate devices. The AngioScuplt was selected as the primary predicate because of the other similarities between the devices.

Technological Characteristic	Proposed Device Tri-Wedge	Predicate Device AngioSculpt UltraScore	Comparison
General Catheter Design	Consists of tip, marker bands, balloon, scoring element, catheter shaft, strain relief, hub. Over-the-Wire (OTW) design	Consists of tip, marker bands, balloon, scoring element, catheter shaft, strain relief, hub. Over-the-Wire (OTW) design	Same
Shaft Design	Dual lumen catheter	Dual lumen catheter	Same
Compatible Guidewire (in)	0.018, 0.035	0.014, 0.018 0.014, 0.035	Same
Compatible Sheath (F)	5, 6, 7	5, 6 4, 5, 6	Different
Balloon Compliance Type	Non-Compliant	Non-Compliant	Same
Balloon Diameter Range (mm)	3.0-8.0	2.0-8.0 2.0-8.0	Same
Balloon Length Range (mm)	20-60	10-200 20-300	Same
Catheter Working Length (cm)	50-150	50-155 40-150	Same
Nominal Pressure (atm)	12	6-8 6-8	Different
Rated Burst Pressure (atm)	16-20	12-20 10-14	Different
Marker Band Present	Yes	Yes Yes	Same
Materials	Proprietary Material Information	Proprietary Material Information	Different
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same

The differences between the proposed device and the predicate device have been thoroughly evaluated through the designed verification and validation tests as listed in below sections.

8. PERFORMANCE TESTING SUMMARY

Standard bench performance tests were conducted to confirm substantial equivalence between the Subject Device and the Predicate Devices.

- Bench Testing

The in vitro performance tests were conducted on subject device in accordance with FDA guidance "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions, Guidance for Industry and FDA Staff ", including:

- Dimensional verification
- Simulated Use
- Balloon Rated Burst Pressure
- Balloon Fatigue & Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Scoring Wire Bond Strength
- Tip Pull Strength
- Flexibility and Kinking
- Torque Strength
- Radiopacity
- Scoring Performance
- Coating Friction & Integrity
- Particulate Evaluation
- Catheter Body Bust Pressure

- Biocompatibility Testing

The biocompatibility testing, conducted in accordance with FDA guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", and International Standard "ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA, included:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity
- Hemocompatibility
  - Hemolysis
  - Thrombosis
  - Complement Activation
- Pyrogenicity

- Sterilization Packaging and Shelf Life

The test results met all acceptance criteria, were same or similar to the predicate devices, and ensure that the Tri-Wedge PTA Scoring Balloon Dilatation Catheter design and construction are suitable for its

intended use. The results also demonstrate that no new questions of safety or effectiveness are raised by the proposed device.

- Animal Study

The animal study was conducted to evaluate the safety of Tri-Wedge PTA Balloon Dilatation Catheter. There was no significant difference between the test group and the control group in the performance of device passage, dilatation, withdrawal and coordination. Histopathological examination showed no difference between the test group and the control group in terms of inflammation score, injury score and endothelialization score.

9. CONCLUSION

Following the comprehensive comparison and analysis conducted, it has been determined that the proposed device does not present new or different questions regarding safety and effectiveness when compared to the predicate device. Consequently, the Tri-Wedge can be considered Substantially Equivalent (SE) to the marketed predicate devices.