February 27, 2025

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

Re: K243704
Trade/Device Name: Parafleet SC 014 PTA Balloon Dilatation Catheter; Parafleet SC 018 PTA Balloon Dilatation Catheter; Parafleet SC 035 PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 28, 2024
Received: November 29, 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,

ARIEL G. ASH-SHAKOOR -S

Digitally signed by ARIEL G. ASH-SHAKOOR -S
Date: 2025.02.27 10:00:55 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243704

Device Name
Parafleet SC 014 PTA Balloon Dilatation Catheter;
Parafleet SC 018 PTA Balloon Dilatation Catheter;
Parafleet SC 035 PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Parafleet SC 014 / Parafleet SC 018 / Parafleet SC 035 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.

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

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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

January 24, 2025

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

Parafleet SC 014 PTA Balloon Dilatation Catheter;
Parafleet SC 018 PTA Balloon Dilatation Catheter;
Parafleet SC 035 PTA Balloon Dilatation Catheter;

2.1.2 Common/Usual Name

Percutaneous Transluminal Angioplasty (PTA) Catheter

2.1.3 Classification Information

Classification Name:	Percutaneous Catheter
Classification Regulation:	21 CFR 870.1250
Device Class:	Class II
Product Code:	LIT
Review Panel:	Cardiovascular

3. PREDICATE DEVICE AND REFERENCE DEVICES

- Primary Predicate Device:
  Polux, Minerva, Atropos PTA Balloon Catheter (K160256, cleared on July 29, 2016)

- Reference Devices:
  Ultraverse 014 and 018 PTA Balloon Dilatation Catheters (K192318, cleared on October 3, 2019)
  Ultraverse 035 PTA Balloon Dilatation Catheter (K142261, cleared on September 24, 2014)
  Sleek OTW PTA Catheter (K102035, cleared on December 1, 2010)

4. DESCRIPTION OF THE DEVICE

The Parafleet balloon dilatation catheter family consists of Parafleet SC 014, Parafleet SC 018 and Parafleet SC 035 PTA balloon catheter. The PTA (OTW type) device is an over the wire (OTW) peripheral balloon catheter, specially designed for Percutaneous Transluminal Angioplasty (PTA). The

Parafleet SC catheter is available in working lengths of 40cm, 70cm, 90cm, 120cm, 150cm and 200cm, with balloon diameters ranging from 1.25mm to 12.0mm. The Parafleet features an outer tube and inner tube lumen shaft ending in a Y-hub manifold with luer lock fittings. 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 a standard 0.014 inch / 0.018 inch / 0.035 inch guide wire insertion. The catheter is sterilized with EO and for single use only. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

5. INDICATION FOR USE

The Parafleet SC 014 / Parafleet SC 018 / Parafleet SC 035 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.

6. COMPARISION SUMMARY WITH PREDICATE DEVICES

The information of subject devices and predicate devices summarized as below **Table 1**.

Table 1 Subject Device & Predicate Devices

Trade Name	Parafleet SC 014, Parafleet SC 018, Parafleet SC 035 PTA Balloon Dilatation Catheter - Proposed device	Polux, Minerva, Atropos PTA Balloon Dilatation Catheter - Predicate device	Ultraverse 014 and 018 PTA Balloon Dilatation Catheters - Reference device	Ultraverse 035 PTA Balloon Dilatation Catheter - Reference device	Sleek OTW PTA Catheter -Reference device
510(K) Number	K243704	K160256	K192318, K121856, K093965	K142261	K102035
Owner/Operator	BrosMed Medical Co., Ltd	BrosMed Medical Co., Ltd	Bard Peripheral Vascular, Inc	Bard Peripheral Vascular, Inc	Clear Stream Technologies, Ltd

The subject devices have the following similarities to the predicate devices:

- Same principle of operation
- Same mechanism of action
- Same indication for use
- Same sterilization method
- Same balloon size
- Similar materials
- Similar device components

Please see below **Table 2** and **Table 3** for the comparison between Subject devices and Predicate devices.

Table 2 General and Intended Use Comparison

Element of Comparison	Proposed device	Predicate device	Reference device	Reference device	Reference device	Judgement
Product Name	Parafleet SC 014, Parafleet SC 018, Parafleet SC 035	Polux, Minerva, Atropos	Ultraverse 014 and 018	Ultraverse 035	Sleek	/
Product Code	LIT	LIT	LIT	LIT	LIT	Same
Regulation Number	870.1250	870.1250	870.1250	870.1250	870.1250	Same
Device Name	Catheter, Angioplasty, Peripheral, Transluminal	Catheter, Angioplasty, Peripheral, Translumina	Catheter, Angioplasty, Peripheral, Transluminal	Catheter, Angioplasty, Peripheral, Transluminal	Catheter, Angioplasty, Peripheral, Transluminal	Same
Target Area	Peripheral arteries and arteriovenous dialysis fistulae	Peripheral arteries and arteriovenous dialysis fistulae	Peripheral arteries and arteriovenous dialysis fistulae	Peripheral arteries and arteriovenous dialysis fistulae	Peripheral arteries and arteriovenous dialysis fistulae	Same
Intended use	The Parafleet SC 014/ Parafleet SC 018/ Parafleet SC 035 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	Polux, Minerva, Atropos are 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. This device is also indicated for dilatation of post-deployed stent in the	Ultraverse 014 and Ultraverse 018 PTA Balloon Dilatation Catheters are recommended for use in percutaneous trasluminal angioplasty (PTA) of the renal, popliteal, tibial, femoral, and peroneal arteries. These catheters are not for use in coronary arteries.	The Ultraverse 035 PTA Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native or synthetic AV fistulae and/or re-expand endoluminal stent graft elements in the iliac arteries. This device is also recommended for post-dilatation of balloon expandable	Balloon dilatation of the femoral, popliteal, and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.	Same with Polux, Minerva, Atropos

	post-deployment in the peripheral vasculature.	peripheral vasculature.		and self-expanding stents in the peripheral vasculature. This catheter is not for use in coronary arteries.		

Table 3 Technological Comparison of Subject Device and Predicate Devices

Technological Characteristic	Proposed Device Parafleet SC 014, Parafleet SC 018, Parafleet SC 035	Predicate/ Reference Devices **Polux, Minerva, Atropos (**K160256), **Ultraverse 014 and 018 (**K192318, K121856, K093965), **Ultraverse 035** (K142261), and **Sleek** (K102035)	**Judgement**
Design and Performance Specification			
General Catheter Design	Consists of tip, marker bands, balloon, catheter shaft, strain relief, hub. Over-the-Wire (OTW) design	Consists of tip, marker bands, balloon, catheter shaft, strain relief, hub. Over-the-Wire (OTW) design	Same
Compatible Guidewire (in)	0.014, 0.018, 0.035	0.014, 0.018, 0.035 (Polux, Minerva, Atropos); 0.014, 0.018 (Ultraverse 014 and 018) 0.035 (Ultraverse 035)	Same
Compatible Sheath (F)	4, 5, 6, 7	4, 5, 6, 7 (Polux, Minerva, Atropos); 4, 5, 6 (Ultraverse 014 and 018) 5, 6, 7 (Ultraverse 035)	Same
Balloon Compliance Type	Semi-Compliant	Semi-Compliant	Same
Balloon Diameter Range (mm)	1.25-12.0	1.5-10.0 (Polux, Minerva, Atropos); 1.5-9.0 (Ultraverse 014 and 018) 3.0-12.0 (Ultraverse 035) 1.25-5.0 (Sleek)	Same
Balloon Length Range (mm)	10-300	5-200 (Polux, Minerva, Atropos); 20-300 (Ultraverse 014 and 018) 20-300 (Ultraverse 035)	Similar
Catheter Working Length (cm)	40-200	40-150 (Polux, Minerva, Atropos); 75-200 (Ultraverse 014 and 018) 75-130 (Ultraverse 035)	Similar
Nominal Pressure (atm)	6	6	Same
Rated Burst Pressure (atm)	12-16	14 (Polux, Minerva, Atropos); 11-16 (Ultraverse 014 and 018) 10-14 (Ultraverse 035)	Similar
Radio-detectability	Yes	Yes	Same
Biological Characteristics			
Tip	Parafleet SC 014 and Parafleet SC 018: Same as predicate device Parafleet SC 035: Similar to predicate device		Substantially Equivalent
Balloon Tubing	Same as predicate device		Same
Catheter Shaft	Similar to predicate device		Substantially Equivalent
Coating	Same as predicate device		Same
Sterilization Method	Ethylene Oxide (EtO)		Same

7. 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
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Tip Pull Strength
- Flexibility and Kinking
- Torque Strength
- Radiopacity
- Coating Friction
- Coating Integrity
- Particulate Evaluation
- Catheter Body Bust Pressure
- Balloon Rated Burst Pressure (in stent)
- Balloon Fatigue (in stent)

- 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 Parafleet SC 014 / Parafleet SC 018 / Parafleet SC 035 PTA Balloon Dilatation Catheter design and construction are suitable for its intended use.

8. CONCLUSION

The information presented in this 510(k) submission demonstrates that the Parafleet SC 014, Parafleet SC 018, and Parafleet SC 035 are Substantially Equivalent (SE) to the marketed predicate devices described above.