July 19, 2022

BrosMed Medical Co., Ltd.
Crystal Lee
Registration Affairs Manager
2nd and 15th Buildings, SMEs Venture Park,
Songshan Lake Hi-Tech Development Zone
Dongguan, Guangdong 523808
China

Re: K212215
Trade/Device Name: Tiche PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: July 9, 2021
Received: July 15, 2021

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,

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)*
K212215

Device Name
Tiche PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The balloon dilatation catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian 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

1. GENERAL INFORMATION

1.1 Submitter

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SongShan Lake Hi-Tech Industrial Development Zone
Dongguan 523808, China
Office: +86 (769) 2289 2018
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1.2 Contract person

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

1.3 Date of Preparation

July 17, 2022

2. INFORMATION OF THE DEVICE

2.1.1 Trade/Proprietary Name
Tiche PTA Balloon Dilatation Catheter

2.1.2 Submission 510(k) number
K212215

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

2.1.4 Classification Information

Classification Name:	Catheters, Angioplasty, Peripheral, Transluminal
Classification Regulation:	21 CFR 870.1250
Device Class:	Class II (Special Controls)
Product Code:	LIT
Review Panel:	Cardiovascular

3. PREDICATE DEVICE AND REFERENCE DEVICES

- Mustang Balloon Dilatation Catheter (K103751, Cleared on March 22, 2011) - Primary predicate device
- Hermes NC PTA Balloon Dilatation Catheter (K160941, Cleared on December 13, 2016) - Reference device

4. DESCRIPTION OF THE DEVICE

The Tiche is an Over the Wire (OTW) peripheral balloon catheter, specially designed for Percutaneous Transluminal Angioplasty (PTA). The device features a low profile balloon and tip. The working length of the catheter range from 40cm-135cm. A hydrophilic coating is applied from the distal tip to the distal shaft. The balloon dilatation catheter features a dual lumen shaft ending in a Y-hub manifold. The balloon has two radiopaque markers for positioning the balloon relative to the stenoses. 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 at specific pressure. 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.

5. INDICATION FOR USE

The indication for use / intended use statement for the Tiche PTA Balloon Dilatation Catheter is as follows:

- The balloon dilatation catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian 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. INTENDED USE COMPARISION SUMMARY

The subject device and the predicate devices, are intended to be used in the same interventional procedures in almost the same peripheral vasculature. Besides, the subject device and the predicate devices have the same primary function of performing post-deployment for the stent dilatation in the peripheral vasculature. Thus, the subject device and the predicate devices have almost identical intended use / indications for use statements. The **Table 5-1** below outlines that the indications for use between the subject and predicate devices that are considered equivalent.

Table 5-1 Intended Use Comparison

Device	Indications for Use	Comparison
Tiche **Subject Device**	The Tiche Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian 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.	Subject Device
PREDICATE DEVICES		
Mustang, K103751 (Primary)	The Mustang Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries. The Mustang Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.	Equivalence
Hermes, K160941 (Reference)	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 for stent dilatation post-deployment in the peripheral vasculature.	Equivalence

7. TECHNOLOGICAL CHARACTERISTICS COMPARISION SUMMARY

There are minor changes to the materials used between subject Tiche PTA Balloon Catheter and predicate devices. These material changes have no significant difference in the safety and clinical performance of the devices according to related justification provided in this submission.

Additionally, the subject device shares the following technological characteristics with the predicate devices. These characteristics are considered identical among the subject and predicates:

- Principle of operation
- Mechanism of action
- Balloon technical specifications including available diameters, lengths, materials, radiopaque makers and rate burst pressures
- Catheter technical specifications including shaft design, compatible guidewire, compatible sheath and all materials except for the shaft material listed in **Table 5-2**
- Packaging configuration
- Sterilization Method

Table 5-2 bellow outlines the characteristics among the subject Tiche device and the predicate devices that are not identical but are considered similar and equivalent.

Table 5-2 Technological Characteristics Comparison

Technological Characteristic	**Subject Device Tiche**	**Predicate Device Mustang, K103751 (Primary); Hermes, K160941 (Reference)**	**Comparison**
Balloon Diameter Range (mm)	3.0-12.0	3.0-12.0 (Mustang); 3.0-10.0	Same as Mustang
Balloon Length Range (mm)	20-200	20-200 (Mustang); 20-150	Same as Mustang
Catheter Working Length (cm)	40, 75, 120, 135	40, 75, 135 (Mustang); 40, 70, 90, 150	Same as Mustang
Nominal Pressure (atm)	10, 12	8, 10 (Mustang); 12	Similar
Rated Burst Pressure (atm)	14-24	14-24 (Mustang); 18-22	Same as Mustang
Balloon Material	Pebax+Nylon	Pebax+Nylon (Mustang); Nylon	Same as Mustang
Coating	Hydrophilic, Silicone	Silicone, Silicone oil (Mustang); Hydrophilic, Silicone	Same as Hermes

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 draft guidance "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions, Draft Guidance for Industry and FDA Staff (FDA-2019-D-5422)", including:

- Dimensional verification
- Simulated Use
- Balloon Rated Burst Pressure
- Balloon Fatigue & Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength

- Tip Pull Strength
- Flexibility and Kinking
- Torque Strength
- Radiopacity
- Coating Friction & 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" issued on September 4, 2020, 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
- Acute Systemic Toxicity
- Hemocompatibility
  - Hemolysis
  - Thrombosis
  - Complement Activation
- Pyrogenicity
- Genotoxicity
  - Bacterial Mutagenicity Test
  - In vitro mouse lymphoma Assay

- Sterilization Packaging and Shelf Life

The test results met all acceptance criteria, were same or similar to the predicate devices, and ensure that the Tiche PTA balloon dilatation catheter design and construction are suitable for its intended use.

9. CONCLUSION

The subject device, the Tiche PTA Balloon Dilatation Catheter met all the predetermined acceptance criteria of the design verification and validation as specified by applicable standards, FDA guidance documents and test protocols. No new questions of safety or effectiveness were raised during the testing program.

Based on the similarities in the indication for use, device design, materials and the results of the non-clinical testing and analysis, the Tiche PTA Balloon Dilatation Catheter is considered substantially equivalent to the the aforementioned primary predicate device.