April 30, 2021

BrosMed Medical Co., Ltd.
% Diane Horwitz
Regulatory Consultant
Eminence Clinical Research Inc.
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K203390
Trade/Device Name: Artimes pro Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX

Dear Diane Horwitz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 14, 2021. Specifically, FDA is updating this SE Letter to remove proprietary information from the 510k summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, 301-796-6075, **Gregory.OConnell@fda.hhs.gov**.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.04.30 13:07:19 -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

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Trade/Device Name: Artimes pro 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 3, 2021
Received: March 5, 2021

Dear Diane Horwitz:

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,

For Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2021.04.14 16:39:41 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203390

Device Name
Artimes pro Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Artimes pro Balloon Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery in patients with myocardial ischemia.

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 and 510(k) Owner

Wade Zhang, 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

1.2 Date of Preparation

April 14, 2021

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

Artimes pro Balloon Dilatation Catheter

2.1.2 Common/Usual Name

Percutaneous Transluminal Coronary Angioplasty (PCTA) Catheters

2.1.3 Classification Information

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

3. PREDICATE DEVICE AND REFERENCE DEVICES

Predicate: Artimes Balloon Dilatation Catheter, BrosMed Medical Co., Ltd., K141025

Reference Devices: Sprinter Legend RX (K103095), Mini Trek Rx (K123279)

4. DESCRIPTION OF THE DEVICE

The Artimes pro (Rx type) device is a coronary dilatation catheter designed for easy guidewire exchange. The catheter working length is 140cm. Lubricious coatings are applied to the distal section. Balloon diameters range from 1.0mm to 1.25mm. The balloon material is made of a semi-compliant material for diameter 1.0mm to 1.25mm with a rated burst pressure of 14 atmospheres. The proximal shaft of the catheter is composed of a female luer connector bonded to a PTFE coated stainless steel tube with a wire. The proximal shaft joins with a smooth transition to a distal shaft composed of an outer tube and a tri-extrusion inner tube with a balloon laser welded to both tubes at the distal tip. The catheter has one radiopaque platinum/iridium marker band. The inner tube accepts a standard 0.014 inch PTCA guidewire. The guide wire enters the catheter tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guide wire. Two marked sections of 5mm length each located on the proximal shaft indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. 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 Artimes pro Balloon Dilatation Catheter is as follows:

> The Artimes pro Balloon Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery in patients with myocardial ischemia.

6. COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Artimes pro Balloon Dilatation Catheter and the predicate device, the Artimes Balloon Dilatation Catheter, are intended to be used in the same interventional procedures in the same target population (patients with narrowing of the coronary arteries and myocardial ischemia) and have the same primary function of performing the initial dilatation of the stenotic portion of the coronary artery. Thus, the subject device and the predicate device have almost identical intended use / indications for use statements.

The intended use for the Subject Device and the Predicate Device are shown in **Table 1** below.

Table 1. Intended Use Comparison

Device	Intended Use
SUBJECT DEVICE	
Artimes pro	The Artimes pro Balloon Dilatation Catheter is indicated for initial balloon dilatation of the stenotic portion of a coronary artery in patients with myocardial ischemia.
PREDICATE DEVICE	
Artimes (K141025)	The Artimes PTCA catheter is indicated for: Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

Comparisons of the Subject Device and the Predicate Devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.

7.1 Similarities and Differences in Technology Comparison

The subject device has the following similarities on technological characteristics to the predicate devices:

- Same principle of operation
- Same catheter design
- Same material of construction
- Same coating
- Similar device dimensions
- Same packaging configuration
- Same method of sterilization
- Same compatibility with other devices

The main technological difference between the Subject and Predicate Device is the Balloon Diameter Range. There are several examples of Reference Devices that have been chosen to show that smaller balloon catheters have been cleared for marketing by FDA and are similar to the Subject Device with respect to the main technological difference: the Mini Trek Rx (K123279) and Sprinter Legend RX (K103095).

BrosMed has demonstrated that the technological differences between the subject device and the predicate device do not raise different issues of safety or effectiveness through bench performance testing and in the clinical trial.

8. PERFORMANCE TESTING

Standard bench performance tests were conducted to confirm substantial equivalence between the Subject Device and the Predicate Device. 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, and particulate evaluation, and also biocompatibility tests, such as cytotoxicity, sensitization, hemocompatibility, pyrogenicity, acute systemic toxicity, intracutaneous reactivity and genotoxocity (bacterial mutagenicity and in vitro mouse lymphoma) were conducted on the Artimes pro PTCA catheter. The test results met all acceptance criteria, were similar to predicate devices, and ensure that the Artimes pro PTCA catheter design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010).

In addition, a GCP clinical study that was conducted with sixty (60) study subjects and sixty-one (61) target lesions to evaluate the safety and effectiveness of Artimes pro Dilatation Catheters. The conclusions from this study support the safety and effectiveness of the Artimes pro balloon dilatation catheter. Both 1.0mm and 1.25mm dilation catheters were effective and functioned as intended. The Artimes pro dilatation catheters demonstrated in this study that both the 1.0mm and 1.25mm dilation catheters are safe for the pre-dilatation of stenoses and occlusions.

9. CONCLUSION

The information presented in this 510(k) submission demonstrates that the Artimes pro PTCA catheter is substantially equivalent to the predicate device.