August 3, 2021

QualiMed USA, LLC.
% Marc Scheineson, Esq
Alston & Bird LLP
950 F Street N.W.
Washington, D.C., District of Columbia 20004

Re: K201246
Trade/Device Name: PTA Balloon Catheter (PVQ), MIT PTA Balloon Catheter (PVQ)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 22, 2021
Received: June 22, 2021

Dear Marc Scheineson:

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)*
K201246

Device Name
PTA Balloon Catheter (PVQ), MIT PTA Balloon Catheter (PVQ)

Indications for Use *(Describe)*
The PTA Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal 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.

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510(k) Summary - K201246

Submitted By:

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CRO

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Date Prepared: August 3rd, 2021

1.1. Trade and or Proprietary Name are the same.

Trade and or Proprietary Name	Model	Note
PTA Balloon Catheter (PVQ):	PVQ 14, PVQ 18, PVQ 18DF, PVQ 35 and PVQ 35HP	For the whole family
MIT PTA Balloon Catheter (PVQ):	PVQ 14, PVQ 18 and PVQ 18DF	For these small sizes only

1.2. Common/Usual Name: Over the wire (OTW) Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter

1.3. Classification Name: Catheter, Angioplasty, Peripheral, Transluminal

1.4. Classification: Class II
Panel: Division of Cardiovascular Devices (DCD)
Peripheral Interventional Devices Branch (PIDB)
Product Code: LIT
Regulation: 21 CFR 870.1250

1.5. Purpose of Submission:
To introduce a line of OTW Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheters (PVQ) to the marketplace.

1.6. Device Description

The PTA Balloon Catheters (PVQ) is a sterile, single use, non-pyrogenic balloon catheter for peripheral indication. The device features an ultra-low profile, semi-compliant balloon combined with a low-profile tip.

The PTA Balloon Catheters (PVQ) has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of 0.014 in (0.36 mm), 0.018 in (0.46mm), guidewires to facilitate advancement of the catheter to and through the stenosis to be dilated. The PTA Balloon Catheters (PVQ) features a dual lumen shaft that provides rapid inflation/deflation times for the catheters compatible with 0.035 in (0.89mm) guidewires. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter includes a tapered tip to facilitate advancement of the catheter. The working lengths of the balloon catheter range between 10 mm and 280 mm, and are selected based on patient requirements for PTA. The radiopaque marker(s) (see RMD in Figure 1) are placed beneath the "usable balloon length" of the balloon and are visible when used in conjunction with fluoroscopy and aid in the placement of the balloon. The effective length could increase by 1 cm in a fully hydrated state.

Each balloon inflates to the stated diameter and length at a specific pressure. The maximum rated burst pressure is different for each size. It is important that the balloon not be inflated beyond the rated burst pressure.

The proximal portion of the catheter includes one female luer-lock port connected to the inflation lumen, and one female luer-lock port for the guidewire lumen. The devices can be supplied with and without hydrophilic coating. The hydrophilic coating when applied is applied proximally to the balloon for a length of 20 mm and 40 mm.

Each PTA Balloon Catheters (PVQ) is packaged as follows:

- The balloon is protected within a protective tube with an inner lumen protective stainless-steel wire.
- The entire catheter is provided in a Polyethylene or Poly propylene Protectivetubing spiral dispenser.
- The protected catheter is placed in a Tyvec pouch, which is sealed to form the sterile barrier.
- Then the pouch is placed into an outer box.

The PTA Balloon Catheters (PVQ) is used with commercially available sheath introducers, guide catheter and guidewires. These are not included with the PTA Balloon Catheter (PVQ).

1.7. Indication for Use:

The PTA Balloon Catheter (PVQ) is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infrapopliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

1.8. Technological Characteristics:

The technological characteristics of the PTA Balloon Catheters (PVQ) are the same as for the predicate and reference devices as they have no significant differences in the materials, sterilization, specifications, design, and intended uses).

1.9. Substantial Equivalence:

The PTA Balloon Catheters (PVQ) are substantially equivalent to the primary predicate device (Cordis Savvy 18 - K971010), and the Bard Ultraverse PTA Catheters (K142261 – 0.035, K121856 – 0.018 and 0.014) as reference devices. The equivalence is supported by the attached documentation.

1.10. Comparison to Predicate Devices:

Characteristics	**PTA Balloon Catheter (PVQ) Q³ Medical Device Limited (Proposed Device)**	**Predicate Device – Cordis Savvy 18 (K971010)**	**Reference Device - Bard Ultraverse 0.014 & 0.018 (K121856)**	**Reference Device - Bard Ultraverse 0.035 (K142261)**	**Comparison**
FDA Product Code	LIT	LIT	LIT	LIT	Same
Indications for Use	The PTA Balloon Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstruction lesions of native or synthetic arteriovenous dialysis fistulae.	The Cordis PTA Catheters are intended for balloon dilatation of lesions in peripheral arteries (iliac, renal, popliteal, infra popliteal, femoral, and ilio-femoral) and are also intended to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	The Ultraverse® 014 & 018 PTA Balloon Dilatation Catheters, are recommended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, 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 and self-expanding stents in the peripheral vasculature. This catheter is not for use in coronary arteries.	Similar

Catheter Design	Over the Wire (OTW)	Over the Wire (OTW)	Over the Wire (OTW)	Over the Wire (OTW)	Same
Ballon Materials	Nylon, Pebax, hydrophilic coating	Nylon, Polyethylene, PTFE	Balloon and Lumen Material: N/A Coating: hydrophilic coating	N/A	Similar
Sheath Size/Fit	4 to 9 (F)	4 to 5 (F)	4 to 5 (F)	5 to 6 (F)	Similar
Compatible Guidewires	0.014, 0.018, 0.018 Dialysis Fistulae, and 0,035	0.018	0.014 & 0.018	0.035	Same
Balloon Diameter	1.25 to 12.0 mm	2 to 6 mm	1.5 to 5 mm	3-12 mm	Similar
Balloon Length	10 to 280 mm	20 to 100 mm	2 to 30 cm (20 mm to 300 mm)	20-300 mm	Similar
Usable Catheter Length	45 to 160 cm	80 to 150 cm	75 to 150 cm	75 to 130 cm	Similar
Nominal Pressure	2.00 to 7.00, bar	6 to 8 atm	N/A	N/A	
Rated Burst Pressure	18 – 22 bar	10 atm	N/A	9 to 21 atm	Similar
lMarker Bands	Dual Pt/Ir Markers	Two Radiopaque Markers	Two Radiopaque Markers	GeoAlign Marker Bands	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same

1.11. Performance Testing:

The PTA Balloon Catheters (PVQ) were designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre- defined acceptance criteria.

To demonstrate substantial equivalence of PTA Balloon Catheters (PVQ) to the predicate devices, the technological characteristics and performance criteria were evaluated using the bench testing recommendations outlined in the FDA Guidance Document "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" dated September 8, 2010. The following performance tests were completed:

- Surface Visual Inspection
- Dimension Verification and Photo Documentation of Catheter and Accessories
- Component Dimension Compatibility
- Trackability
- Pushability
- Simulated Use Test:
    - Passage
    - Flex/Kink
    - Torqueability
- 2 Point Bending
- 3 Point Bending

- Deflation Time and Rate
- Nominal Pressure
- Rated Burst Pressure
- Dynamic Friction
- Friction of guidewire lumen
- Kink Resistance
- Conical Fitting Test/Luer Lock Stress Test
- Bond Strength
- X-Ray Visibility
- Biocompatibility
- Bioburden
- Endotoxine
- Haemolysis

The results of these tests demonstrate the technological characteristics and performance criteria of the PTA Balloon Catheters (PVQ) are adequate for its intended use, and is substantially equivalent to the predicate devices.

1.12. Conclusion

QualiMed USA has concluded that the information provided supports that the PTA Balloon Catheters (PVQ) are substantially equivalent to the predicate and reference devices.