

510(k) Summary  
[As required by 21 CFR 807.92(c)]

AUG 17 2011

## 1. Submitter's Name / Contact Person

Submitter: TriReme Medical, Inc.  
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Date Prepared: July 20, 2011

## 2. General Information

Trade Name: GliderXtreme™ PTA Balloon Catheter and GliderfleX™ PTA Balloon Catheter

Common/Usual Name: Angioplasty Catheter

Classification Name: Percutaneous Catheter (21 CFR 870.1250)

Product Code: DQY / LIT

510(k) number:

Predicate Devices: VasuTrak PTA Dilatation Catheter (K082343)

EverCross 0.035" OTW PTA Dilatation Catheter (K082519)

GliderXtreme PTA Balloon Catheter (K101062)

GliderfleX PTA Balloon Catheter (K103534)

## 3. Intended Use

The PTA Balloon Catheter family is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

## 4. Device Description

All of the devices in the PTA Balloon Catheter family, including the GliderXtreme PTA Balloon Catheter and the GliderfleX PTA Balloon Catheter consist of a standard balloon dilatation catheter on a braided shaft with or without a hypotube and an atraumatic, tapered and beveled tip. The devices are compatible with commonly used accessories, including standard 0.014" and 0.018" guidewires and 5F or 6F introducer sheath (or 6F or 7F guide catheter). Overall catheter lengths are approximately 100 cm to 150cm.

The distal end has a semi-compliant balloon that expands to known diameters (refer to compliance chart) at specific pressures. The balloon contains radiopaque markers to assist with positioning. The shaft is braid reinforced and has a lubricious hydrophilic coating.

The proximal end of the device is a common PTA catheter connected to a plastic hub and strain relief. The hub is used to inflate the balloon; the luer connector is compatible with standard inflation devices.

All PTA Balloon Catheters in the family are supplied sterile and intended for single use only.

#### 5. Performance Data

Bench testing was performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

The following *in vitro* tests were performed:

- Balloon Rated Burst Pressure
- Balloon Inflation and Deflation
- Balloon Fatigue
- Catheter Body Strength (Bond Strength)
- Torsional Strength
- Catheter Diameter, Balloon Profile and Tip Configuration
- Balloon Compliance
- Trackability, Pushability
- Kink Resistance
- Device Interface Compatibility

#### 6. Substantial Equivalence Comparison and Conclusion

The additional balloon sizes of the GliderXtreme™ and GliderfleX™ PTA Balloon Catheters are substantially equivalent to the predicate devices in design, materials, packaging, fundamental scientific technology, manufacturing, sterilization and intended use. Performance testing demonstrated that the devices reliably achieved the desired effect and is safe for its intended use. No new questions of safety or effectiveness were identified during device testing. Therefore, additional sizes of the GliderXtreme™ and GliderfleX™ PTA Balloon Catheters are considered substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WQ66-G609  
Silver Spring, MD 20993-0002

TriReme Medical, Inc.  
c/o William Sammons  
Intertek Testing Services NA, Inc.  
2307 E Aurora Rd, Unit B7  
Twinsburg, OH 44087

AUG 17 2011

Re: K112281

Trade/Device Name: GliderXtreme and GliderfleX PTA Balloon Catheters  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II (two)  
Product Code: DQY, LIT  
Dated: 8 August 2011  
Received: 9 August 2011

Dear Mr. Sammons:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (XXXXX): K112281

Device Name: GliderXtreme PTA Balloon Catheter and GliderfleX PTA Balloon Catheter

Indications for Use:

The PTA Balloon Catheter Family of devices, including the GliderXtreme PTA Balloon Catheter and the GliderfleX PTA Balloon Catheter are intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

The indication for use is same for all devices in the PTA Balloon Catheter Family.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JL L  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K112281