



Food and Drug Administration  
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April 7, 2016

TransAortic Medical, Inc.  
% Diana DeGregorio  
Regulatory Affairs Consultant  
135 E. Main Ave., Suite 170  
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Re: K152194  
Trade/Device Name: transGlide Expandable Introducer  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: Class II  
Product Code: DYB  
Dated: March 7, 2016  
Received: March 8, 2016

Dear Diana DeGregorio:

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 contact the Division of Industry and Consumer Education 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>. 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 <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 Industry and Consumer Education 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,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

**510(k) Number (if known):** K152194

**Device Name:** transGlide Expandable Introducer

**Indications for Use:**

The transGlide Expandable Introducer is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters and/or devices introduced into the femoral iliac arteries.

**Prescription Use**   X                        **Or**                      **Over-The-Counter Use** \_\_\_\_\_  
(per 21 CFR 801.109)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

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## K152194 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

### I. SUBMITTER

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*Date Prepared*

August 3, 2015

### II. DEVICE

Trade Name: transGlide Expandable Introducer  
Common Name: Catheter Introducer  
Classification Name: Catheter Introducer  
Classification: 21 CFR§ 870.1340  
Product Code: DYB  
Device Class: Class II

**III. PREDICATE**

Terumo (formerly Onset Medical Corporation) Solo Path® Balloon Expandable TransFemoral Introducer (K100819)

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

**IV. DEVICE DESCRIPTION**

TransAortic Medical, Inc. is the manufacturer of the transGlide Expandable Introducer, a device intended as a guide for catheters and/or devices introduced into the femoral iliac arteries.

The transGlide Expandable Introducer consists of an expandable Mesh Assembly and a flexible Sheath Assembly. The Mesh Assembly, with an indwelling Dilator, is inserted into the femoral artery over a 0.035" (or smaller) guidewire. The Mesh Assembly is introduced at a small diameter of 13F inner diameter (ID) and is designed with a hydrophilic coating on the outer diameter (OD) of the usable length (effective length), thus facilitating passage through the femoral artery. The proximal 11cm of the Mesh is sealed to prevent blood loss at the access site. Once at the target location, the Mesh Dilator is removed and the Sheath Assembly is inserted, with an indwelling Dilator, through the Mesh Assembly over the guidewire.

Prior to removal, the Sheath Assembly is withdrawn through the Mesh Assembly until the Sheath Removal Indicator is visible just proximal to the Docking Port, leaving 8cm of Sheath usable length in place to prevent blood loss while the entire assembly is withdrawn and removed from the patient.

The Mesh consists of a polymer braid, which expands to accommodate the profile of the Sheath. The Mesh provides a bearing surface for the Sheath, which is designed to reduce the axial forces applied to the artery wall while the Sheath is being inserted. The Sheath Assembly Dilator is removed leaving a large (16F, 18F or 20F) central lumen extending from the proximal end to the distal end of the Sheath with a usable length of 30cm.

The transGlide Expandable Introducer is a sterile, non-pyrogenic, single-use prescription device. The transGlide Expandable Introducer does not supply but recommends use with commercially available 0.035" (or smaller) Guidewires.

**V. INDICATIONS FOR USE**

The transGlide Expandable Introducer is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters and/or devices introduced into the femoral iliac arteries.

**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The transGlide Expandable Introducer has similar features as compared to the predicate device as shown in the following table:

Manufacturer	Terumo (formerly Onset Medical Corporation)	TransAortic Medical, Inc.
Model Name	SoloPath® Balloon Expandable TransFemoral Introducer	transGlide Expandable Introducer
510(k) Number	K100819	TBD
Intended Use	To provide an access conduit for the introduction of devices into the peripheral vasculature	To provide an access conduit for the introduction of devices into the peripheral vasculature
Indication for Use	The SoloPath Balloon Expandable TransFemoral Introducer is intended to be inserted percutaneously into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters and/or devices introduced into the femoral iliac arteries.	The transGlide Expandable Introducer is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters and/or devices introduced into the femoral iliac arteries.
Product Code	DYB 21 CFR 870.1340 Catheter Introducer Class II	DYB 21 CFR 870.1340 Catheter Introducer Class II
Anatomical Locations	Peripheral Vasculature	Same
French Sizes Available	14–21F	16–20F
Usable Length	25–35cm	30cm
Expansion Mechanism	injecting fluid through the applicable port to inflate balloon	insertion of sheath through mesh
Insertion Profile	Outer Diameter: 3.8–5.0mm (11.5–15F)	Outer Diameter: 5.0mm (15F)
Expansion Profile	Inner Diameter: 4.7– 7.0mm (14–21F) Outer Diameter: 5.7– 8.0mm (17–24F)	Inner Diameter: 5.3–6.7mm (16– 20F) Outer Diameter: 6.7–8.0mm (20– 24F)
Materials	<ul style="list-style-type: none"> <li>• Polymer Sheath (reinforced with stainless steel ribbon) with radiopaque marker</li> <li>• Polymer Hub with Hemostasis Valve and Extension Tube/3-Way Stopcock</li> <li>• Polymer Sheath Dilator with balloon and proximal Luer</li> <li>• Hydrophilic coating</li> </ul>	<ul style="list-style-type: none"> <li>• Polymer Sheath with radiopaque marker and removal indicator</li> <li>• Polymer Hub with Hemostasis Valve and Extension Tube/3-Way Stopcock</li> <li>• Polymer Sheath Dilators with Luer</li> <li>• Expandable polymer Mesh</li> <li>• Polymer Docking Port with Seal</li> <li>• Polymer/Stainless Steel Mesh Dilator with Luer</li> <li>• Hydrophilic coating</li> </ul>
Radiopacity	Radiopaque marker at distal tip	Same
Sterilization Method	EO	Gamma Irradiation

<b>Manufacturer</b>	<b>Terumo (formerly Onset Medical Corporation)</b>	<b>TransAortic Medical, Inc.</b>
<b>Model Name</b>	<b>SoloPath® Balloon Expandable TransFemoral Introducer</b>	<b>transGlide Expandable Introducer</b>
<b>510(k) Number</b>	<b>K100819</b>	<b>TBD</b>
<b>Placement</b>	Standard techniques for placement of vascular access sheaths	Same
<b>Guidewire compatibility</b>	0.038" (or smaller) compatible guidewire	0.035" (or smaller) compatible guidewire

The technological characteristics and principals of operation of the transGlide Expandable Introducer is substantially equivalent to the named predicate device.

## VII. PERFORMANCE DATA

The following performance testing was conducted on the transGlide Expandable Introducer to support a determination of substantial equivalence to the predicate device.

### Biocompatibility

- Cytotoxicity: MEM Elution (L-929)
- Sensitization: Magusson-Kligman Method
- Irritation: Intracutaneous Toxicity (ISO)
- Systemic Toxicity: Systemic Injection (ISO)
- Hemocompatibility:
  - Thrombogenicity
  - Complement Activation C3a and SC5b-9
  - Partial Thromboplastin Time
  - Hemolysis (Direct and Extract)
- Pyrogenicity
  - Material Mediated Pyrogen
  - Bacterial Endotoxins-Limulus Amebocyte Lysate (LAL)

### Bench Testing

- Visual Inspection and Dimensional Verification
- Flush Testing
- Simulated Use: Advancement, Dilator Removal, Retraction & Inspection
- Leak Testing (BS EN 11070:1999)
- Bend/Kink Resistance Testing
- Radiopacity Testing
- Interventional Device Advancement and Removal
- Hydrophilic Coating Lubricity
- Hydrophilic Coating Durability

- Hydrophilic Coating Particulate Characterization
- Hub to Sheath Rotation
- Tensile Tests (BS EN 11070:1999)
- Corrosion Testing (BS EN 11070:1999)
- Packaging Validation (BS EN ISO 11607-111607-1:2009 + A1:2014)
- Sterilization Validation (ANSI/AAMI/ISO 11137-2:2013)
- Shelf Life

#### Animal Studies

A GLP animal study was performed to evaluate the safety and performance of the transGlide Expandable Introducer as compared to a control device (Terumo SoloPath® Balloon Expandable TransFemoral Introducer (K100819)) in an ovine model. Based on pathology and histopathology results, the safety acceptance criteria for the study were met. Performance observations were made based on detailed characteristics of the device. No untoward observations were found by the clinician.

#### **VIII. CONCLUSIONS**

The transGlide Expandable Introducer has been carefully compared to the legally marketed predicate device with respect to intended use/indications for use, technological characteristics, anatomical sites, performance, safety characteristics, and labeling. In addition, non-clinical testing was conducted to verify and validate the performance of the device and ensure the transGlide Expandable Introducer functions as intended and meets design specifications. The comparison, non-clinical and clinical performance testing results demonstrate that the device is substantially equivalent to the predicate device for its intended use.