March 26, 2019

TransAortic Medical, Inc.
c/o Ms. Diana DeGregorio
Regulatory Affairs Consultant
Lince Consulting, LLC
135 E. Main Ave., Suite 170
Morgan Hill, CA 95037

Re: K181817
   Trade/Device Name: transGlideXT Expandable Introducer
   Regulation Number: 21 CFR 870.1340
   Regulation Name: Catheter Introducer
   Regulatory Class: Class II
   Product Code: DYB
   Dated: February 15, 2019
   Received: February 19, 2019

Dear Ms. 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. 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 h\lps\t://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Misti L. Malone –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

The transGlideXT 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.
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
TransAortic Medical, Inc.
135 E. Main Avenue
Suite 170
Morgan Hill, CA 95037
Phone: (408) 779-4200
Fax: (408) 779-4288

Contact Person
Diana DeGregorio
Lincé Consulting, LLC
Regulatory Affairs Consultant
Phone: (925) 980-8047
ddegregorio@linceconsulting.com

Alternate Contact:
Nancy Lincé
Regulatory & Clinical Affairs Consultant
Lincé Consulting, LLC
Phone: (650) 759-6186
nlince@linceconsulting.com

Date Prepared
July 6, 2018

II. DEVICE
Trade Name: transGlideXT Expandable Introducer
Common Name: Catheter Introducer
Classification Name: Catheter Introducer
Classification: 21 CFR§ 870.1340
Product Code: DYB
Device Class: Class II
III. PREDICATE
TransAortic Medical, Inc. transGlide Expandable Introducer (K152194)
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 transGlideXT Expandable Introducer, a device intended as a guide for catheters and/or devices introduced into the femoral iliac arteries.

The transGlideXT Expandable Introducer (also referred to as “transGlideXT”) is the next generation expandable Mesh Introducer consisting of a polymer braid which expands to accommodate catheters and/or devices with profiles up to 22F. The Mesh Introducer, with an indwelling Dilator (also referred to as “Mesh Assembly”), is inserted into the femoral artery, over a 0.035” guidewire (or smaller). The device is introduced at a small diameter of 12F inner diameter (ID) and is designed with a hydrophilic coating on the outer diameter (OD) and ID along the 30 cm usable length, thus facilitating passage through the femoral artery and passage of the commercial catheter and/or device. The proximal 11 cm of the Mesh usable length is sealed to prevent blood loss at the access site. Once at the target location, the Dilator is removed and the Mesh Introducer provides a bearing surface for the commercial catheter and/or device, which is designed to reduce the axial forces applied to the artery wall while the commercial catheter and/or device is being inserted.

The transGlideXT Expandable Introducer is a sterile, non-pyrogenic, single-use prescription device. The transGlideXT Expandable Introducer does not supply but recommends use with commercially available 0.035” (or smaller) Guidewires.
V. INDICATIONS FOR USE
The transGlideXT 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 subject and predicate devices are designed 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. The subject device requires fewer procedural steps compared to the predicate as there is no introduction of a separate Sheath Assembly required. The primary difference between the previously cleared transGlide and the transGlideXT models is the removal of the Sheath Assembly and associated modification to the Mesh Assembly. The transGlideXT model is being offered to provide an Introducer that can accommodate devices up to 22F with fewer procedural steps and an effective thinner insertion profile.

A summary table comparing the subject and predicate device is provided in Table 1.

<table>
<thead>
<tr>
<th>Manufacturer Model Name 510(k) Number</th>
<th>TransAortic Medical, Inc. transGlide Expandable Introducer K152194</th>
<th>TransAortic Medical, Inc. transGlideXT Expandable Introducer K181817</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>To provide an access conduit for the introduction of devices into the peripheral vasculature</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>Same</td>
</tr>
<tr>
<td>Product Code</td>
<td>DYB 21 CFR 870.1340 Catheter Introducer Class II</td>
<td>Same</td>
</tr>
<tr>
<td>Anatomical Locations</td>
<td>Peripheral Vasculature</td>
<td>Same</td>
</tr>
<tr>
<td>French Sizes Available</td>
<td>16-20F</td>
<td>Up to 22F</td>
</tr>
<tr>
<td>Usable Length</td>
<td>30cm</td>
<td>Same</td>
</tr>
<tr>
<td>Expansion Mechanism</td>
<td>Insertion of sheath through mesh</td>
<td>Insertion of catheter or device through mesh</td>
</tr>
<tr>
<td>Insertion Profile</td>
<td>Inner Diameter: 4.3mm (13F) Outer Diameter: 5.0mm (15F)</td>
<td>Inner Diameter: 4.0mm (12F) Outer Diameter: 4.7mm (14F)</td>
</tr>
<tr>
<td>Manufacturer Model Name 510(k) Number</td>
<td>TransAortic Medical, Inc. transGlide Expandable Introducer K152194</td>
<td>TransAortic Medical, Inc. transGlideXT Expandable Introducer K181817</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>---------------------------------------------------------------</td>
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</tr>
<tr>
<td>Expansion Profile</td>
<td>Inner Diameter: 5.3–6.7mm (16–20F) Outer Diameter: 6.7–8.0mm (20–24F)</td>
<td>Inner Diameter: up to 7.3mm (up to 22F) Outer Diameter: up to 8.3mm (up to 25F)</td>
</tr>
<tr>
<td>Materials</td>
<td>• Polymer Sheath with radiopaque marker and removal indicator • Polymer Hub with Hemostasis Valve and Extension Tube/3-Way Stopcock • Polymer Sheath Dilators with Luer • Expandable polymer Mesh • Polymer Docking Port with Seal • Polymer/Stainless Steel Mesh Dilator with Luer • Hydrophilic coating</td>
<td>• Expandable polymer Mesh with radiopaque marker • Polymer Hub with Hemostasis Valve and Extension Tube/3-Way Stopcock • Polymer/Stainless Steel Mesh Dilator with Luer • Hydrophilic coating</td>
</tr>
<tr>
<td>Radiopacity</td>
<td>Radiopaque marker at distal tip</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Gamma Irradiation</td>
<td>Ethylene Oxide</td>
</tr>
<tr>
<td>Placement</td>
<td>Standard techniques for placement of vascular access sheaths</td>
<td>Same</td>
</tr>
<tr>
<td>Guidewire compatibility</td>
<td>0.035&quot; (or smaller) compatible guidewire</td>
<td>Same</td>
</tr>
</tbody>
</table>

**VII. PERFORMANCE DATA**

The following performance testing was conducted on the transGlideXT 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
Animal Studies
A series of in vivo evaluations were performed to evaluate the safety and performance of the transGlideXT Expandable Introducer as compared to the transGlide Expandable Introducer predicate device in the ovine model. Testing Methods and acceptance criteria were consistent with the animal testing performed and submitted for the predicate (K152194). The results of the in vivo chronic and acute studies confirm that the transGlideXT Expandable Introducer is functional and safe for its intended use when used in accordance with the manufacturers labeling. In addition, the results demonstrate that the transGlideXT Expandable Introducer safety and functionality is comparable to the transGlide Expandable Introducer (predicate). 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.

VIII. CONCLUSIONS
The transGlideXT 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 transGlideXT 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.