510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92(c) and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. Submitter's Name	Abbott Vascular
2. Submitter's Address	3200 Lakeside Drive Santa Clara, CA 95054
3. Telephone	(408) 845-0937
4. Fax	(408) 845-3734
5. Contact Person	Makena Mc Gowan
6. Date Prepared	August 7, 2017
7. Device Trade Name	Steerable Guide Catheter
8. Device Common Name	Steerable Catheter
9. Device Classification Name	Catheter, Steerable
10. Predicate Device Name	K083793 Steerable Guide Catheter K091596 Steerable Guide Catheter K093866 Steerable Guide Catheter K100789 Steerable Guide Catheter K112239 Steerable Guide Catheter K161985 Steerable Guide Catheter

11. Device Description

The Steerable Guide Catheter consists of a Guide and a Dilator provided EtO sterile and for single use only. The Steerable Guide Catheter consists of a distal and proximal catheter shaft, a radiopaque tip ring, a handle with a steering knob, a hemostasis valve with a luer lock flush port, an atraumatic distal tip, and a Dilator with a single central lumen. The central lumen of the Guide allows for aspiration of air and infusion of fluids such as saline, and serves as a conduit during introduction and or exchange of the Dilator and ancillary devices (e.g. catheters) that have a maximum diameter of .204". The atraumatic distal tip of the Steerable Guide Catheter is radiopaque to allow visualization under fluoroscopy. The Dilator consists of a radiopaque shaft, an echogenic feature at the distal tip, a hemostasis valve with a flush port and an internal lumen designed to accept ancillary devices that have a maximum diameter of 0.035" (e.g. needles or guidewires). The Steerable Guide Catheter, Dilator and accessories are packaged in a tray that is individually pouched in a Tyvek/Nylon corner peel pouch, heat-sealed one time, and the single sealed pouch is placed into a cardboard nest and top-loading box.

The subject 510(k) pertains to a design change to the Steerable Guide Catheter. The proposed change to the Steerable Guide Catheter consists of a design and processing modification to the internal feature of the tip ring component at the distal tip.

12. Indication for Use

The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

13. Technological Characteristics

Comparison of the new device and predicate device demonstrate that the technological characteristics such as the fundamental scientific technology, material, and indications for use are substantially equivalent to the current marketed predicate device.

14. Performance Data

Tensile strength evaluation of the catheter tip was conducted on predicate (unmodified) and subject (modified tip) devices to demonstrate that the subject device meets performance specifications and is substantially equivalent to the predicate Steerable Guide Catheter.

Process validation was conducted to demonstrate that the manufacturing process consistently produces subject devices that meet performance specifications.

15. Conclusions

The Steerable Guide Catheter has the same indications for use and performs as well as the predicate device.