



May 29, 2019

Abbott  
Ms. Ekta Lad  
Sr. Specialist Regulatory Affairs  
3200 Lakeside Drive  
Santa Clara, California 95054

Re: K190167  
Trade/Device Name: Steerable Guide Catheter  
Regulation Number: 21 CFR 870.1280  
Regulation Name: Steerable Catheter  
Regulatory Class: Class II  
Product Code: DRA  
Dated: April 29, 2019  
Received: May 1, 2019

Dear Ms. Lad:

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/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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Nicole Ibrahim

Director

DHT2B: Division of Circulatory Support,  
Structural and Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K190167

Device Name  
Steerable Guide Catheter

### Indications for Use (Describe)

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 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) 845-8132
4. Fax (408) 845-3734
5. Contact Person Ekta Lad
6. Date Prepared May 22, 2019
7. Device Trade Name Steerable Guide Catheter
8. Device Common Name Steerable Catheter
9. Classification Regulation Number: 21 CFR 870.1280
10. Product Code DRA
11. Predicate Device Name K172394 Steerable Guide Catheter

### 12. 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 0.204". 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.

### 13. 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.

#### 14. Comparative Technology Characteristics

A comparison of the characteristics of the proposed device and predicate device show the Steerable Guide Catheter to have the same technological characteristics to the current cleared predicate device. Equivalence is based upon intended use, indications for use, principles of operation and fundamental technology.

The subject and predicate device have similar or identical materials of composition, dimensions, and sterilization. Changes between the device and predicate include a minor design modification, packaging, and shelf life.

#### 15. Performance Data

Testing was performed to support substantial equivalence, including:

Biocompatibility

Sterilization

Packaging

Performance

Shelf Life

#### 16. Conclusion

The subject Steerable Guide Catheter is equivalent to the predicate device. This conclusion is based upon the fact that the devices have an equivalent intended use, and there are no differences that raise different questions of safety and effectiveness.