



August 07, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular
Makena Mc Gowan
Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, California 95054

Re: K161985

Trade/Device Name: Steerable Guide Catheter
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: July 18, 2016
Received: July 19, 2016

Dear Ms. Mc Gowan:

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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman", is written over a faint, large "FDA" watermark.

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

510(k) Number (if known)

K161985

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.

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510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.1280 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 4, 2016
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

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 enclosed in a sealed Tyvek pouch and boxed in a cardboard shelf-carton.

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 design, material, and indications for use are substantially equivalent to the current marketed predicate device.

14. Performance Data

The Steerable Guide Catheter is equivalent in fundamental scientific design to the predicate Steerable Guide Catheter, and therefore, meets the same performance specifications as the predicate device.

15. Conclusions

The Steerable Guide Catheter has the same indications for use and technological characteristics and is substantially equivalent to the predicate device.