September 28, 2022

Abbott
Irma Barr
Senior Specialist Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95054

Re: K221397
Trade/Device Name: MitraClip G4 Steerable Guide Catheter
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: September 2, 2022
Received: September 6, 2022

Dear Ms. Barr:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jaime Raben, PhD
Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221397

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 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.

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510(k) SUMMARY

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

I. SUBMITTER

Abbott Medical
177 County Road B East
St. Paul, Minnesota 55117 USA

Phone (201) 787-2054
Contact Person: Irma Barr
Date Prepared: August 15, 2022

II. DEVICE

Name of Device: Steerable Guide Catheter
Common Name: Steerable Catheter
Classification Name: Catheter, Steerable
Regulatory Class: II
Product Code: DRA

III. PREDICATE DEVICE

K190167 Steerable Guide Catheter

IV. DEVICE DESCRIPTION

The Steerable Guide Catheter (including a dilator) 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 device provides a conduit into the left side of the heart through the interatrial septum. The Steerable Guide Catheter is provided EtO sterile and for single use only.

V. INDICATIONS FOR USE

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

VI. COMPARISON OF TECHNOLOGICAL 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 minor design modifications and shelf life.

VII. PERFORMANCE DATA

Testing was performed to support substantial equivalence, including:

Performance
Shelf Life

VIII. 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.