August 26, 2024

Abbott Medical
Irma Barr
Senior Specialist, Regulatory Affairs
177 County Road B East
St. Paul, Minnesota 55117

Re: K241538
Trade/Device Name: TriClip Steerable Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 30, 2024
Received: May 30, 2024

Dear Irma 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241538

Device Name

TriClip™ Steerable Guide Catheter

Indications for Use *(Describe)*

The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the right side of the heart.

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 (855) 478-5833
Contact Person: Irma Barr
Date Prepared: May 30, 2024

II. DEVICE

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

III. PREDICATE DEVICE

AMPLATZER® TorqVue® Low Profile Delivery System (K131063)

IV. REFERENCE DEVICE

MitraClip G4 Steerable Guide Catheter (K221397)

V. DEVICE DESCRIPTION

The TriClip 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 right side of the heart. The distal shaft is steered using a handle and knobs.

The TriClip Steerable Guide Catheter is compatible with devices (e.g., catheters) with a maximum diameter of 5.2 mm (0.204”), and the Dilator is compatible with devices (e.g., needles or guidewires) with a maximum diameter of 0.9 mm (0.035”).

The TriClip Steerable Guide Catheter consists of materials including nylon, stainless steel, polycarbonate, PVP coating, silicone, urethane, PVC, and Pebax. The distal shaft has a hydrophilic coating to provide a lubricated surface for ease of insertion.

The TriClip Steerable Guide Catheter is provided EO sterile and for single use only.

VI. INDICATIONS FOR USE

The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the right side of the heart.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices are handheld catheter systems designed to facilitate access and placement of specified devices within the chambers and coronary vasculature of the heart. A comparison of the intended use and technological characteristics demonstrates that the TriClip Steerable Guide Catheter is substantially equivalent to the AMPLATZER TorqVue Low Profile Delivery System (K131063) and MitraClip G4 Steerable Guide Catheter (K221397).

The TriClip Steerable Guide Catheter and the AMPLATZER TorqVue Low Profile Delivery System have the same intended uses and sterilization methods. They have similar design features such as the hemostasis valve and are compatible with guide wires, but the AMPLATZER system does not include a dilator and has a radiopaque catheter body rather than a radiopaque tip.

The TriClip Steerable Guide Catheter and MitraClip G4 Steerable Guide Catheter are equivalent in terms of design, material, principle of operation, and sterilization method. There are minor differences in design to facilitate access to different areas of the heart.

VIII. SUBSTANTIAL EQUIVALENCE

The following performance testing was performed to demonstrate the device meets its design specification and is as safe and effective as the predicate device. The following design verification and validation testing was provided in support of a substantial equivalence determination. Performance testing was leveraged from the MitraClip G4 Steerable Guide Catheter where appropriate.

Biocompatibility

The biocompatibility evaluation of the TriClip Steerable Guide Catheter was conducted in accordance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The device is considered an external communicating device with limited (≤24 hour) contact with circulating blood, therefore, evaluation was conducted in the following categories:

- Cytotoxicity
- Hemocompatibility
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Materials-Mediated Pyrogenicity

Design Verification

The following bench testing was conducted to demonstrate that the TriClip Steerable Guide Catheter met all performance specifications:

- Visual inspection
- Catheter dimensions
- Curves and steering performance
- Tensile strengths
- Torsional strengths
- Hemostasis
- Particulate evaluation
- Shelf-life verification

Sterilization

The TriClip Steerable Guide Catheter is intended for single use only and is provided sterile via ethylene oxide (EO) gas to achieve a Sterility Assurance Level (SAL) of 10^{-6} per ISO 11135. An EO/ECH residuals assessment found the residuals to be acceptable per ISO 10993-7 following 2X sterilization.

Packaging

Packaging verification studies were performed in compliance with the applicable requirements of ISO 11607-1 and ISO 11607-2. All device packaging met acceptance criteria following 2X sterilization, environmental conditioning, and transport simulation.

IX. CONCLUSION

The subject TriClip Steerable Guide Catheter is substantially equivalent to the predicate device. This conclusion is based upon the devices' similarities in intended use and technological characteristics. There are no differences between the subject device and the predicate that raise new questions for safety and effectiveness.