April 25, 2025

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

Re: K250426
Trade/Device Name: Amulet™ Steerable Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 13, 2025
Received: February 14, 2025

Dear Meghann Kayoum:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

LYDIA S. GLAW -S

Digitally signed by LYDIA S. GLAW -S
Date: 2025.04.25 16:45:22 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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)*
K250426

Device Name
Amulet™ Steerable Delivery Sheath

Indications for Use *(Describe)*
The Amulet™ Steerable Delivery Sheath is indicated to facilitate the delivery of the Amplatzer™ Amulet™ Left Atrial Appendage Occluder.

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 INFORMATION

Submitter Name: Abbott Medical
Submitter Address: 177 County Road B East
St. Paul, MN 55117 USA
Phone: (651) 756-5833

Contact Person: Meghann Kayoum
Date Prepared: 13 February 2025

II. DEVICE

Name of Device: Amulet™ Steerable Delivery Sheath
Common Name: Catheter Delivery Sheath
Classification Name: Catheter, Percutaneous (21 CFR 870.1250)
Device Class: II
Product Code: DQY

III. PREDICATE DEVICES

Primary Predicate: Amulet™ Steerable Delivery Sheath (K232690, cleared 29 September 2023)

IV. DEVICE DESCRIPTION

The Amulet™ Steerable Delivery Sheath is designed to provide a pathway through which a device may be delivered. The sheath is provided in one size (14F), with a working length of 75 cm and a bi-directional distal tip to provide positioning in the cardiac anatomy. The handle is equipped with a deflection knob to deflect the tip clockwise 120° and counterclockwise 0°. The body of the sheath is radiopaque for visibility under fluoroscopy and has a marker band located in the distal tip. The dilator eases penetration of tissue. The sheath and dilator utilize a dual curve in two dimensions, resulting in a three-dimensional geometry. The 14F flush adapter facilitates the attachment of additional components.

V. INDICATIONS FOR USE

The Amulet™ Steerable Delivery Sheath is indicated to facilitate the delivery of the Amplatzer™ Amulet™ Left Atrial Appendage Occluder.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Amulet Steerable Delivery Sheath incorporates substantially equivalent design, function, packaging, sterilization process, materials, fundamental technology, indication for use, and operating principles as those shared by the predicate Amulet Steerable Delivery Sheath (K232690).

A comparison of the proposed Amulet Steerable Delivery Sheath and the predicate Amulet Steerable Delivery Sheath show these devices have substantially equivalent design characteristics, including a deflectable sheath, dilator, and adapter. The difference between the subject device and predicate is the in-process solvent used to prepare the surface of the distal tip PEBAX extrusions. Additionally, a tip bond tensile specification and in-process tensile test method are being implemented. The tip bond tensile specification aligns with currently defined product requirements.

510(k) SUMMARY

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following testing was provided in support of a substantial equivalence determination.

Process Qualification

Product performance qualification (PPQ) testing was conducted to demonstrate that the Amulet Steerable Delivery Sheath met performance specifications impacted by these changes, including:

- Number of Occluder Retrievals
- Delivery Sheath and Implant Damage
- Tensile Bonds During Handoff/Advancement

Biocompatibility

A biocompatibility safety evaluation of the Amulet Steerable Delivery Sheath was conducted in accordance with the FDA Guidance: Use of International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2023), ISO 10993-1, ISO 14971, and ASTM F2475. No new materials of construction were introduced with this change, and the subject device has identical patient contact types and durations and the predicate device. Potential risks identified with changing the surface preparation chemical present negligible risk to the established biocompatibility profile of the device, and no further testing was required.

Sterilization and Microbiology

The Amulet Steerable Delivery Sheath 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. There are no proposed changes to the sterilization method, sterilization facilities, packaging system, product design, or materials of construction with this change. A microbiology product assessment evaluated the microbiological impact of this change and determined there is no increased microbiological or sterilization risk. The currently established SAL of 10^{-6} is not impacted by this change.

VIII. CONCLUSION

Based on the indication for use, technological characteristics, and non-clinical performance testing provided, the subject Amulet Steerable Delivery Sheath device is substantially equivalent to the predicate Amulet Steerable Delivery Sheath (K232690). The Amulet Steerable Delivery Sheath should perform as intended in the specified use conditions.