September 29, 2023

Abbott Medical
Dan Gapp
Regulatory Affairs Project Manager
177 County Road B East
St. Paul, Minnesota 55117

Re: K232690
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: September 1, 2023
Received: September 1, 2023

Dear Dan Gapp:

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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2023.09.29 07:42:12 -04'00'

for Rachel Neubrander
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)*
K232690

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: Dan Gapp
Date Prepared: 28 September 2023

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: Amplatzer™ Steerable Delivery Sheath (K220340, cleared 09 March 2022)

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 Amplatzer Steerable Delivery Sheath (K220340).

A comparison of the Amulet Steerable Delivery Sheath and Amplatzer 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 subject device does not include an integrated hemostasis valve and sideport.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following design verification and validation testing was provided in support of a substantial equivalence determination. Components not impacted by the design changes did not undergo additional testing.

Biocompatibility

The biocompatibility 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:

510(k) SUMMARY

Evaluation and testing within a risk management process" (2020), ISO 10993-1, ISO 14971 and ASTM F2475. The device is considered an external communicating device with limited (≤24 hour) contact with circulating blood, therefore evaluation was conducted in the following categories:

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

Design Verification

Bench testing, including shelf life testing, was conducted to demonstrate that the Amulet Steerable Delivery Sheath met all performance specifications, including:

- Tensile Testing
- Torque Testing
- System Leak
- Dimensional
- Device Compatibility
- Luer Compatibility
- Handoff Force
- System Prep
- Visual Requirements
- Air Introduction

Sterilization

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. The Amulet Steerable Delivery Sheath was adopted into routine cycles used to sterilize the primary predicate device, the Amplatzer Steerable Delivery System, based on a comparison of composition, packaging, design, pallet density, and bioburden levels per ANSI/AAMI TIR 28. An EO/ECH residuals assessment found the residuals to be acceptable with respect to the predicate device per ANSI/AAMI/ISO 10993-7, following 2X sterilization.

Packaging

Packaging verification studies were performed in compliance with the applicable requirements of ASTM F2825, ASTM D4332, ASTM F2096; F1886/F1886M and ASTM F88/F88M. All device packaging met acceptance criteria following 2X sterilization, environmental conditioning and transport simulation.

Design Validation

A design validation study was performed to evaluate the Amulet Steerable Delivery Sheath to deliver an Amplatzer Amulet Left Atrial Appendage Occluder. In a benchtop simulated use model, physicians who have experience with left atrial appendage devices evaluated the performance of the Amulet Steerable Delivery Sheath to deliver the Amplatzer Amulet Left Atrial Appendage Occluder. The protocol acceptance criteria were met.

Human Factors

A Human Factors evaluation of the Amulet Steerable Delivery Sheath was performed to confirm the design changes did not introduce any new user-device interactions per the requirements of ANSI/AAMI/IEC 62366-1. This evaluation did not observe any patterns of use errors or identify any new user-device interactions compared to the predicate device.

VIII. CONCLUSION

Based on the indication for use, technological characteristics and non-clinical performance testing provided, the Amulet Steerable Delivery Sheath is substantially equivalent to the predicate Amplatzer Steerable Delivery

510(k) SUMMARY

Sheath (K220340). The Amulet Steerable Delivery Sheath should perform as intended in the specified use conditions.