March 9, 2022

Abbott Medical
Emily Jallen
Regulatory Affairs Specialist II
5050 Nathan Lane N
Plymouth, Minnesota 55442

Re: K220340
Trade/Device Name: Amplatzer™ Steerable Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 2, 2022
Received: February 7, 2022

Dear Emily Jallen:

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,

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)*
K220340

Device Name
Amplatzer™ Steerable Delivery Sheath

Indications for Use *(Describe)*
The Amplatzer™ 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.

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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: 5050 Nathan Lane North
Plymouth, MN 55442
USA
Phone: +1 (651) 756-3583
Contact Person: Emily Jallen
Date Prepared: February 2, 2022

II. DEVICE

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

III. PREDICATE DEVICES

Primary Predicate: Amplatzer™ Steerable Delivery Sheath (K212026, cleared September 27, 2021)

IV. DEVICE DESCRIPTION

The Amplatzer Steerable Delivery Sheath is a sterile (EO), single use sheath designed to provide a pathway through which a device may be delivered. The delivery sheath is available in one size, 14F. The sheath will be used to deliver an Amplatzer Amulet™ Left Atrial Appendage Occluder. The Amplatzer™ Steerable Delivery Sheath is comprised of three components: a sheath to deliver the device, a dilator to ease penetration of tissue, and a 2X to 1X Flush Adapter to facilitate connection of additional device components.

The sheath is comprised of the distal tip, sheath body and sheath handle. The distal tip design utilizes a dual fixed curve in two dimensions, resulting in a three-dimensional geometry. The sheath body is radiopaque for visibility under fluoroscopy and includes a marker band located in the distal tip to aid with visualization during device deployment and recapture. The Steerable Sheath device has been designed with a bi-directional distal tip which is controlled by pull-wires along the sheath body connected to the device handle to provide better co-axial alignment between the appendage and sheath, allowing for more accurate device placement. Additionally, a hemostasis valve and side port are integrated in the device handle to support improved procedural hemostasis control and ease of use. The sheath has an effective length of 75 cm and 98.5 cm overall length. The sheath is compatible with a 0.35” guidewire and a 19F introducer.

This Special 510(k) is being submitted to add additional precautions and updated procedural steps to the Instructions for Use (IFU) of the Amplatzer Steerable Delivery Sheath.

V. INDICATION FOR USE

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

There are no changes in technological characteristics from the predicate device.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

A Human Factors evaluation of the Amplatzer Steerable Delivery Sheath was performed to confirm that the updated IFU did not introduced any new user-device interactions per the requirements of ANSI/AAMI/IEC 62366-1. It was concluded that use of the Amplatzer Steerable Delivery Sheath with the updated IFU remains safe and effective for the intended users, uses, and use environments.

VIII CONCLUSION

As there are no changes in the indication for use, intended use, technological characteristics, the Amplatzer Steerable Delivery Sheath is substantially equivalent to the primary predicate device (K212026). The Amplatzer Steerable Delivery Sheath should perform as intended in the specified use conditions.