September 27, 2021

Abbott Medical
Dan Gapp
Regulatory Affairs Project Manager
5050 Nathan Lane North
Plymouth, Minnesota 55442

Re: K212026
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: June 25, 2021
Received: June 29, 2021

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 (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 E. Neubrander -S

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)*
K212026

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: 651 756 3329 (Office)
612 289 8887 (Mobile)
Contact Person: Dan Gapp
Date Prepared: June 25, 2021

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: TorqVue™ 45x45 Delivery Sheath (K163000, cleared December 23, 2016)

Reference Predicate: Agilis™ NxT Steerable Introducer (K081645, cleared June 11, 2008)

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. Additionally, a hemostasis valve and side port are integrated in the device handle. 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.

V. INDICATION FOR USE

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

The Indication for Use of the Amplatzer Steerable Delivery Sheath is not identical to the primary predicate, the TorqVue 45x45 Delivery Sheath, however the differences do alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Amplatzer Steerable Delivery Sheath incorporated substantially equivalent design, function, packaging, sterilization process, materials, fundamental technology, indication for use, intended use and operating principles as those shared by the primary predicate device, the TorqVue 45x45 Delivery Sheath (K163000), and the reference predicate device, the Agilis NxT Steerable Introducer (K081645).

A comparison of the Amplatzer Steerable Delivery Sheath and the TorqVue 45x45 Delivery Sheath shows that these devices have substantially equivalent design characteristics, including the sheath, dilator and 2x to 1x Flush Adapter. The design characteristics of the Agilis NxT Steerable Introducer, including the handle, distal sheath tip deflection, hemostasis valve, flushing sideport with 3-way stopcock are substantially equivalent to those of the Amplatzer Steerable Delivery Sheath.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following design verification and validation testing was provided in support of a substantial equivalence determination.

Biocompatibility testing:

The biocompatibility evaluation of the Amplatzer 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" (2020), ISO 10993-1, ISO 14971 and ASTM F2475-11. Testing was conducted in the following categories:

- Cytotoxicity
- Sensitization
- Irritation
- Acute System Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

The Amplatzer Steerable Delivery Sheath is considered an external communicating device with limited (≤24 hour) contact with circulating blood. All in-vivo and in-vitro testing was conducted in accordance with FDA Good Laboratory Practices (GLP) Regulations, 21 CFR 58.

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

- Dimensional
- Handle Torque to Failure
- Handle Actuation Torque
- Shaft Compression
- Simulated Use
- Tensile Testing
- Sheath Torque
- Hemostasis Valve Leak Rate
- Hemostasis Valve Torque
- System Preparation / De-Air
- System Leak
- Legibility and Durability of Markings
- Amplatzer Steerable Sheath Reflow
- Amplatzer Steerable Tip Stability
- Label Indelibility & Adherence
- Particulate Assessment
- Luer testing (ISO 80369)

Sterilization:
The Amplatzer Steerable Delivery Sheath is intended for single use only and is provided sterilize by ethylene oxide (EO) gas to achieve a Sterility Assurance Level (SAL) of 10^{-6} per ISO 11135. A comparative resistance study demonstrated the suitability of IPCD and EPCDs currently used in routine validated sterilization cycles. The Amplatzer Steerable Delivery Sheath was adopted to routine cycles used to sterilize the primary predicate device, the TorqVue 45x45 Delivery Sheath, based on a comparison of composition, packaging, design, pallet density, and bioburden levels. EO/ECH residuals testing was conducted to support the packaging design of the Amplatzer Steerable Delivery Sheath per ANSI/AAMI/ISO 10993-7. EO and ECH residual test results for the Amplatzer Steerable Delivery Sheath met the requirements of ISO 10993-7 following 2X sterilization.

Packaging:
Packaging verification studies were performed in compliance with the applicable requirements of ASTM F2825-15, ASTM F2096-11; F1886/F1886M-16 and ASTM F88/F88M-15. All device packaging evaluated met acceptance criteria following 2X sterilization, extreme conditioning and transit simulation.

Design Validation:
A design validation study was performed in an acute canine model to evaluate the Amplatzer Steerable Delivery Sheath to deliver an Amplatzer Amulet Left Atrial Appendage (LAA) Occluder. Two independent physicians who have experience with left atrial appendage (LAA) devices evaluated the performance of the Amplatzer Steerable Delivery Sheath to deliver the Amplatzer Amulet Left Atrial Appendage (LAA) Occluder in two animals. Three Amplatzer Steerable Delivery Sheaths were evaluated by each physician. There were no observations or clinically significant comments noted by either of the two physician evaluators during the design validation animal study.

A Human Factors evaluation of the Amplatzer Steerable Delivery Sheath was performed to confirm that the design changes 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 is safe and effective for the intended users, uses, and use environments.

VIII CONCLUSION

Based on the indication for use, intended use, technological characteristics and non-clinical performance testing provided, the Amplatzer Steerable Delivery Sheath is substantially equivalent to the primary predicate device, the TorqVue 45x45 Delivery Sheath (K163000), and the reference predicate device, the Agilis NxT Steerable Introducer (K081645). The Amplatzer Steerable Delivery Sheath should perform as intended in the specified use conditions.