September 27, 2021

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

Re: K212738
Trade/Device Name: Amplatzer™ Talisman™ Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 27, 2021
Received: August 30, 2021

Dear Daniel 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212738

Device Name
Amplatzer Talisman Delivery Sheath

Indications for Use *(Describe)*
The Amplatzer Talisman Delivery Sheath is indicated to provide a pathway through which an Amplatzer PFO Occluder is introduced for patent foramen ovale closure

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
Contact Person:	Daniel Gapp
Phone:	651 756 3329
Email:	dan.gapp@abbott.com
Date Prepared:	27 August 2021

II. DEVICE

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

III. PREDICATE DEVICE

Predicate Device: Amplatzer™ Trevisio™ Intravascular Delivery System (K190581, cleared on 05 April 2019)

IV. DEVICE DESCRIPTION

The Amplatzer Talisman Delivery Sheath is a line extension of the Amplatzer Trevisio Intravascular Delivery System. The Amplatzer Talisman Delivery Sheath is a single use sheath intended to facilitate the delivery and deployment of the Amplatzer Talisman PFO Occluder. The delivery sheath is available in 8F and 9F sizes with a 45° curve and 80 cm usable length. The sheath and dilator are radiopaque for visibility under fluoroscopy. For added visibility the sheath also has a platinum/iridium marker band near the distal tip. The Talisman Delivery Sheath is comprised of two components: a dilator to ease penetration of tissue and minimize vessel trauma, and a sheath to provide a pathway through which an Amplatzer occluder is delivered

V. INDICATION FOR USE

The Amplatzer Talisman Delivery Sheath is indicated to provide a pathway through which an Amplatzer™ PFO Occluder is introduced for patent foramen ovale closure.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Amplatzer Talisman 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 Amplatzer Trevisio Intravascular Delivery System (K190581).

A comparison of the Amplatzer Talisman Delivery Sheath and the Amplatzer Trevisio Intravascular Delivery System Trevisio™ Intravascular Delivery System shows that these devices have identical characteristics, including the sheath and dilator.

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 Talisman 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. Testing was conducted in the following categories:

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

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

Design Verification

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

- Dimensional
- System Leak
- Handoff Force
- Guidewire Compatibility
- System Prep/De-air
- Particulate Assessment
- Sheath Integrity
- Advancement Force
- Recapture Force
- Number of Recaptures
- Luer Testing (80369)
- Label Indelibility & Adherence
- Shelf Life

Sterilization

The Amplatzer Talisman 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 Amplatzer Talisman Delivery Sheath was adopted into routine cycles

used to sterilize the primary predicate device, the Trevisio 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 evaluated met acceptance criteria following 2X sterilization, environmental conditioning and transport simulation.

Design Validation

Two design validation studies were performed to evaluate the Amplatzer Talisman Delivery Sheath to deliver an Amplatzer Talisman PFO Occluder. In a benchtop simulated use model, independent physicians experienced with cardiac interventional procedures evaluated the performance of the Amplatzer Talisman Delivery Sheath to deliver the Amplatzer Talisman PFO Occluder. There were no observations or clinically significant comments noted by the physician evaluators during this design validation study.

Additionally, an acute animal study was also conducted to evaluate the performance of the Amplatzer Talisman Delivery Sheath to deliver an Amplatzer Talisman PFO Occluder. Independent physicians experienced with cardiac interventional procedures evaluated one Amplatzer Talisman Delivery Sheath through simulated use of delivering an Amplatzer Talisman PFO Occluder. There were no observations or clinically significant comments noted by either of the two physician evaluators during this design validation study.

Human Factors

A Human Factors evaluation of the Amplatzer Talisman Delivery Sheath was performed to confirm no new user-device interactions were introduced per the requirements of ANSI/AAMI/IEC 62366-1.

VIII CONCLUSION

Abbott Medical considers the Amplatzer Talisman Delivery Sheath to be substantially equivalent to the Amplatzer Trevisio Intravascular Delivery System. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.