December 17, 2025

Abbott Medical
Nicolette Pedersen
Regulatory Affairs Specialist II
177 County Road B East
St. Paul, Minnesota 55117

Re: K252417
Trade/Device Name: Amplatzer Piccolo™ Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 31, 2025
Received: August 1, 2025

Dear Nicolette Pedersen:

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.12.17 13:36:02 -05'00'

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252417

Device Name
Amplatzer Piccolo Delivery System

Indications for Use *(Describe)*
The Amplatzer Piccolo™ Delivery System is indicated to facilitate the delivery of an Amplatzer Piccolo™ Occluder through the heart of a patient with a patent ductus arteriosus.

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- Traditional 510(k)

The 510(k) summary is submitted in accordance with 21 CFR 807.92.

I. SUBMITTER INFORMATION

Submitter Name:	Abbott Medical
Submitter Address:	177 County Road B East St. Paul, MN 55117 USA
Phone:	(224) 289-2911
Contact Person:	Nicolette Pedersen
Date Prepared:	31 July 2025

II. DEVICE

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

III. PREDICATE DEVICE

Predicate Device:	Amplatzer™ TorqVue™ LP Catheter (K162228)

IV. DEVICE DESCRIPTION

The Amplatzer Piccolo Delivery System is designed to facilitate the delivery of an Amplatzer Piccolo™ Occluder into a patent ductus arteriosus (PDA). The Amplatzer Piccolo Delivery System consists of a delivery catheter, loader, Tuohy-Borst hemostasis valve with extension tube and stopcock, and self-sealing hemostasis valve. The Amplatzer Piccolo Delivery System is available in a 4 Fr size with a usable length of 45 cm. The delivery system components have the following performance characteristics:

- Delivery catheter: Provides a pathway through which an occluder is delivered. The body of the catheter is radiopaque for visibility under fluoroscopy. The distal end of the catheter has a curve that is optimized to allow co-axial placement of the delivery catheter within the PDA. A curve indicator is located on the hub as an additional reference for the direction of the curvature.
- Tuohy-Borst hemostasis valve with extension tube and stopcock: Allows flushing of the delivery catheter and controls blood backflow.
- Loader: Introduces an occluder into the delivery catheter.
- Self-sealing hemostasis valve: Allows flushing of the loader and delivery catheter and controls blood backflow.

V. INDICATIONS FOR USE

The Amplatzer Piccolo™ Delivery System is indicated to facilitate the delivery of an Amplatzer Piccolo™ Occluder through the heart of a patient with a patent ductus arteriosus.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Amplatzer Piccolo Delivery System incorporates substantially equivalent design, function, packaging, sterilization process, materials, fundamental technology, indication for use, and operating principles as the predicate Amplatzer TorqVue LP Catheter (K162228). The Amplatzer Piccolo Delivery System and Amplatzer TorqVue LP Catheter have the same general components and connections between components that form the finished device. The similarities in components provide a similar user interface with the device, and the same principles of operation are used to achieve the intended use. Technological differences include different device dimensions, materials, and minor design elements.

VII. PERFORMANCE DATA

The following non-clinical performance testing is provided in support of a substantial equivalence determination.

Biocompatibility testing

The following biological tests were performed on the finished device to address each relevant biological effect:

- Cytotoxicity (MEM elution)
- Sensitization (guinea pig maximization)
- Irritation (intracutaneous reactivity)
- Material-mediated pyrogenicity
- Acute systemic toxicity
- Hemolysis (direct and extract)
- Complement activation
- *In vivo* thrombogenicity

All established acceptance criteria were met for these tests, demonstrating that the Amplatzer Piccolo Delivery System is biocompatible for its intended clinical use.

Design Verification

Non-clinical bench testing and simulated use testing were conducted at nominal and aging conditions to demonstrate the Amplatzer Piccolo Delivery System meets all product requirements through a shelf life of 3 years.

- Torquability
- Kink resistance
- Air introduction
- Surface inspection
- Tensile strength
- Handoff force
- Advancement force
- Recapture force
- System leak
- Simulated use
- Dimensional
- Loading force
- Distal curve orientation marker
- Marker band location
- Luer compliance
- Particulate
- Device integrity

All established acceptance criteria were met for these tests, demonstrating that the Amplatzer Piccolo Delivery System meets all product requirements.

Packaging
Packaging design verification testing was conducted at nominal and aging conditions to demonstrate the packaging configuration meets all product requirements through a shelf life of 3 years. All testing met acceptance criteria, demonstrating acceptable packaging integrity.

Sterilization
The Amplatzer Piccolo Delivery System 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.

Design Validation
Design validation testing was performed to demonstrate the Amplatzer Piccolo Delivery System conforms to the defined customer requirements and intended uses. All study endpoints in the design validation studies were met demonstrating the Amplatzer Piccolo Delivery System conforms with the applicable customer requirements.

VIII. CONCLUSION

Based on the indications for use, intended use, technological characteristics and non-clinical performance testing provided, the Amplatzer Piccolo Delivery System is substantially equivalent to the predicate device, the Amplatzer TorqVue LP Catheter (K162228). The Amplatzer Piccolo Delivery System should perform as intended in the specified use conditions.