October 3, 2025

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

Re: K250031/S001
Trade/Device Name: Amplatzer Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 3, 2025
Received: September 3, 2025

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.

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,

LYDIA S. GLAW -S

Digitally signed by LYDIA S. GLAW -S
Date: 2025.10.03 11:02:06 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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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)*
K250031

Device Name
Amplatzer Guidewire

Indications for Use *(Describe)*
The Amplatzer Guidewire is intended to facilitate the introduction and exchange of a delivery system or catheter within the vasculature and chambers of the heart.

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.

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: 03 September 2025

II. DEVICE

Name of Device: Amplatzer™ Guidewire
Common Name: Catheter Guide Wire
Device Class: Class II
Product Code: DQX
Product Regulation: 21 CFR 870.1330

III. PREDICATE DEVICE

Predicate Device: Pre-Formed Guidewire, K151244

Reference Devices: Cardiovascular and Vascular Guidewires, K935170
PTFE Guidewire, K242824

IV. DEVICE DESCRIPTION

The Amplatzer™ Guidewire is 0.035-inch in diameter and made of a stainless steel core and a full length stainless steel spring coil coated with low-friction polytetrafluoroethylene (PTFE). The stainless steel core extends to the distal tip of the guidewire for one model (9-GW-001). Two models (9-GW-002 and 9-GW-003) have a stainless steel core that does not extend to the distal end of the wire. These models have an additional ribbon wire that runs parallel to the stainless steel core and extends to the distal end of the guidewire. The stainless steel core for all three models is tapered at the distal end of the guidewire to provide a smooth transition to the distal floppy segment.

The guidewires are available in two working lengths, 260 cm (9-GW-001 and 9-GW-002) and 300 cm (9-GW-003). The distal tip of the guidewire is available in two designs: a Modified J-Tip (9-GW-001) and a J-Tip (9-GW-002 and 9-GW-003). The J-straightener can be used to

straighten the distal tip for all models. Model 9-GW-003 can also be manually straightened. The guidewire is sterile and for single use only.

V. INDICATIONS FOR USE

The Amplatzer™ Guidewire is intended to facilitate the introduction and exchange of a delivery system or catheter within the vasculature and chambers of the heart.

VI. COMPARISON OF SUBJECT DEVICE TO PREDICATE DEVICE

The Amplatzer™ Guidewire has the same intended use as the predicate device, the Pre-Formed Guidewire. The technological differences between the subject and predicate devices do not raise any new or different questions of safety or effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The Amplatzer™ Guidewire was evaluated through performance testing, which included non-clinical bench testing and *in vivo* animal testing.

Biocompatibility

The biocompatibility evaluation of the Amplatzer™ Guidewire 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,*" (issued September 2023). Biocompatibility material assessment was conducted for the constituent materials of the device and any potential chemical residues. Evaluation was conducted in the following categories:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

Design Verification

Bench testing, including shelf-life testing, was conducted to demonstrate that the Amplatzer™ Guidewire met all performance specifications. Verification testing included the following:

- Tensile Strength
- Lubricity
- Coating Integrity
- Visual Assessment
- Bending Durability (Flexing)
- Fracture
- Corrosion Resistance
- Dimensional
- Particulates
- Radiopacity

- Torque Fatigue
- Kink Resistance
- Linear Stiffness
- Body Stiffness
- Tip Shape & Shapeability
- Packaging Performance

Design Validation

A benchtop anatomical model was used to evaluate simulated use of the Amplatzer™ Guidewire. The acceptance criteria were met.

Testing was performed in accordance with 21 CFR Part 58. A pre-clinical swine model was used to demonstrate that the Amplatzer™ Guidewire met the intended use and study objectives.

VIII. CONCLUSION

The Amplatzer™ Guidewire met all design input requirements. Based on the intended use, technological characteristics, and performance testing provided, the Amplatzer™ Guidewire is substantially equivalent to the predicate device, the Pre-Formed Guidewire (K151244).