June 17, 2026

Abbott Medical
Nicolette Pedersen
Senior Specialist Regulatory Affairs
177 County Rd. B E.
Saint Paul, Minnesota 55117

Re: K261631
Trade/Device Name: Amplatzer TorqVue Exchange System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 15, 2026
Received: May 18, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.17 15:30:32 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261631

Device Name
Amplatzer TorqVue Exchange System

Indications for Use *(Describe)*
The Amplatzer TorqVue Exchange System is intended for removal of a delivery sheath and subsequent exchange with a delivery sheath of equal or larger diameter.

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

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	224-289-2911
Contact Person	Nicolette Pedersen
Date Prepared	May 15, 2026

II. DEVICE

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

III. PREDICATE DEVICES

Primary Predicate: Amplatzer™ TorqVue™ Exchange System (K080994, cleared May 16, 2008).

IV. DEVICE DESCRIPTION

The Amplatzer™ TorqVue™ Exchange System is designed to deliver Amplatzer™ occluders. The occluder and exchange system are shipped separately. The body of the sheath is radiopaque for visibility under fluoroscopy.

V. INDICATIONS FOR USE

The Amplatzer TorqVue Exchange System is intended for removal of a delivery sheath and subsequent exchange with a delivery sheath or equal or larger diameter.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Amplatzer TorqVue Exchange System incorporates substantially equivalent design, function, packaging, sterilization process, materials, fundamental technology, indication for use, and operating principles as those shared by the predicate Amplatzer TorqVue Exchange System (K080994).

A comparison of the predicate and subject devices shows they have substantially equivalent design characteristics, including identical sheath, dilator, delivery cable, loader and cable vise components provided with the device. The differences between the predicate and subject device are in the hemostasis valve component which involves removal of an adapter, geometry updates, and material changes. The differences have been demonstrated to be substantially equivalent to the predicate. 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.

510(k) SUMMARY

VII. PERFORMANCE DATA

The following testing was provided in support of a substantial equivalence determination.

Biocompatibility

A biocompatibility evaluation 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" (2023), ISO 10993-1, ISO 14971 and ASTM F2475. Evaluation was conducted in the following categories:

- Hemocompatibility
- Cytotoxicity
- Sensitization
- Irritation
- Materials-Mediated Pyrogenicity
- Acute Systemic Toxicity
- Particulate Evaluation

All established acceptance criteria were met for these tests, demonstrating the Amplatzer TorqVue Exchange System is biocompatible for its intended use.

Design Verification

Non-clinical bench testing was conducted to demonstrate the changes to the Amplatzer TorqVue Exchange System met all product specifications through a shelf life of 3 years, including:

- Dimensional
- System Leak
- Tensile Strength
- Luer Compliance

Sterilization

The Amplatzer TorqVue Exchange 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. An EO/ECH residuals and comparative resistance assessment found the changes did not impact the residuals or ability to achieve a SAL of 10^{-6} compared to the predicate device.

Packaging

Packaging verification studies were performed in compliance with the applicable requirements of ASTM F2825, ASTM D4332, and ASTM D4169. All device packaging met acceptance criteria following sterilization, environmental conditioning and transport simulation.

VIII. CONCLUSION

Based on the indication for use, technological characteristics and non-clinical performance testing provided, the subject Amplatzer TorqVue Exchange System is substantially equivalent to the predicate Amplatzer TorqVue Exchange System (K080994). The Amplatzer TorqVue Exchange System should perform as intended in the specified use conditions.