April 10, 2026

Protaryx Medical, Inc
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K260839
Trade/Device Name: Protaryx Transseptal Puncture Device (PTX2-001)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB, DXF
Dated: February 23, 2025
Received: March 13, 2026

Dear Prithul Bom:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Katherine N. Trivedi -S

Digitally signed by Katherine N. Trivedi -S
Date: 2026.04.10 16:30:06 -06'00'

Katherine Trivedi
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)*
K260839

Device Name
Protaryx Transseptal Puncture Device (PTX2-001)

Indications for Use *(Describe)*
The Protaryx Transseptal Puncture Device is used to introduce various cardiovascular catheters to the heart, including the left side of the heart. The device enables left heart access through a puncture of the atrial septum during a transseptal catheterization procedure.

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

K260839

Submitter Information

Company Name: Protaryx Medical, Inc.
Company Address: 323 West Camden Street, Suite 600, Baltimore, MD 21201, USA
Company Phone: +1 (514) 554- 9628
Company Facsimile: N/A
Contact Person: David Mester, CEO
Summary Prepared on: April 10, 2026

Device Identification

Device Trade Name: Protaryx Transseptal Puncture Device (PTX2-001)
Device Common Name: Introducer
Classification Name: Introducer, Catheter (21 CFR 870.1340)
Product Code: DYB and DXF
Review Panel: Cardiovascular
Device Class: Class II

Identification of Legally Marketed Device(s)

Primary Predicate Device: SafeCross Transseptal Puncture Device and Introducer System (TSP/I)
Manufacturer: East End Medical Inc.
510(k): K203459
Indications for Use: The SafeCross Transseptal Puncture Device and Introducer (TSP/I) System is used to introduce various cardiovascular catheters to the heart, including the left side of the heart. The system enables left heart access through a puncture of the atrial septum during a transseptal catheterization procedure. In addition, the device can be used for monitoring intracardiac pressures, sampling blood, and infusing solutions.

Secondary Predicate Device: VersaCross RF Wire (ProTrack RF Anchor Wire)
Manufacturer: Boston Scientific Inc.
510(k): K242076
Indications for Use: The ProTrack RF Anchor Wire is indicated for the creation of an atrial septal defect in the heart.

Reference Device: VersaCross Transseptal Sheath
Manufacturer: Boston Scientific Inc.
510(k): K183655
Indications for Use: The VersaCross Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation /puncture.

Indications for Use

The Protaryx Transseptal Puncture Device is used to introduce various cardiovascular catheters to the heart, including the left side of the heart. The device enables left heart access through a puncture of the atrial septum during a transseptal catheterization procedure.

Device Description

The Protaryx Transseptal Puncture device is a sterile, single-use introducer catheter device. The device is comprised of a sheath, a dilator, and a pigtail guidewire.

The Protaryx Transseptal Puncture device is designed for catheterization and angiography of specific heart chambers and locations. It is used in catheterization procedures primarily by Electrophysiologists and Interventional Cardiologists. Procedures using the devices are performed in fully equipped catheter labs with imaging equipment, including fluoroscopy and echocardiography under sterile technique.

Comparison of Predicate Devices
The intended use for the Protaryx Transseptal Puncture device is substantially equivalent to the primary predicate device - East End Medical SafeCross device. The secondary predicate device and reference device - Boston Scientific VersaCross RF Wire (ProTrack RF Anchor Wire) and Boston Scientific VersaCross Transseptal Sheath were used to support the basis for substantial equivalence.

The Protaryx Transseptal Puncture Device combines the features/ functions of these devices into a single device. The proposed and predicate devices share the same fundamental scientific technology, including principles of operation and mechanism of action (see Table 1 below) using an RF Guidewire as the means of access. The differences in design and technological characteristics between the proposed and predicate devices do not raise different questions of safety and effectiveness. The results of verification and validation testing demonstrate substantial equivalence of the Protaryx Transseptal Puncture device with the combined predicate devices.

Table 1: Comparison of Subject and Predicate Device

Characteristic	Comparison Results
Intended Use	Identical
Indications for Use	Similar
Fundamental Scientific Technology	Identical
Operating Principles	Identical
Mechanism of Action	Identical
Materials	Similar
Technological Aspects	Similar
Packaging and Sterilization	Similar

Performance Testing Summary
Performance Testing has been completed to demonstrate substantial equivalence of the subject device and predicate device. All test requirements were met as specified by applicable standards and the test protocols. The device was subjected to the following verification and validation activities.

- Performance and Physical Testing:
  Mechanical verification testing was conducted for the subject Protaryx Transseptal Puncture Device to ensure compliance with the requirements of ISO 10555-1 and Protaryx Medical, LLC self-enforced requirements. The following tests were performed:
  - Dimensional verification
  - Simulated Use
  - Catheter Bond Strength
  - Tip Pull
  - Tensile Strength
  - Flexibility and Kink
  - Torque Strength/Response
  - Corrosion resistance
  - Shapeability
  - Surface Defects
  - Hemostasis testing
- Usability testing (via a GLP (21CFR58) Animal study)Biological Safety Testing
  The biological safety of the subject device was verified in accordance with the requirements of ISO 10993-1:2009/Cor.1:2010 and the September 2023 FDA guidance document, Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity

- Acute Systemic Toxicity
- Hemocompatibility (Hemolysis, Complement Activation)
- Thromboresistance
- Material Mediated Pyrogenicity

- Sterilization
  Sterilization verification was completed for the subject device to the requirements of ISO 11135-1:2014. Sterilization is performed with Ethylene Oxide to a Sterility Assurance Level (SAL) of 10^{-6}. Residual limits are in accordance with ISO 10993-7:2008/Cor.1:2009.

- Packaging Validation and Shelf Life
  - Visual inspection, Bubble Leak and Seal Strength testing was used to evaluate the integrity of the packaging configuration. Testing was conducted after sterilization, environmental conditioning, and simulated shipping and distribution. Ship testing was performed to ensure the integrity of the device packaging through the rigors of shipping and handling. The seal strength and sterile barrier integrity was validated per ANSI/AAMI/ISO 11607:2006 (Parts 1 and 2) over the proposed shelf life of the device.

- Pyrogen Testing
  - The subject device is supplied non-pyrogenic. LAL testing using the Kinetic Chromogenic method was conducted to ensure the device meets current FDA and USP pyrogen limit specifications.

- Bench-top Validation.
  - Bench-top validation testing was conducted to assess valve durability of the sheath, radiopacity, compatibility with other devices and to evaluate the design and function.

Conclusion

The intended use and fundamental scientific technology, including principles of operation and mechanism of action, of the Protaryx Transseptal Puncture device is equivalent in form, fit and function to that of the cited Predicates (Safe Cross Transseptal Puncture and Introducer (TSP/I), the VersaCross RF Wire (ProTrack RF Anchor Wire) and the VersaCross Transseptal Sheath). Differences in design and technological characteristics do not raise any different questions of safety and effectiveness. The results of verification and validation activities support the substantial equivalence of the Protaryx Transseptal Puncture Device to the predicate devices.