

K260839 Protaryx Transseptal Puncture Device (PTX2-001)Apr 10, 2026
28 days to decisionK260839 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k260839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 13, 2026
Decision date	Apr 10, 2026
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Protaryx Medical, Inc.
Location	Baltimore, MD, US
Contact	David Mester
Website	https://www.protaryx.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Protaryx Medical, Inc. develops differentiated transseptal access devices for minimally invasive left heart interventional therapies. The company is based in Baltimore, Maryland, and focuses on streamlining workflow efficiency for catheter-based cardiac procedures. The company has received FDA 510(k) clearance from total submission. Protaryx specializes in Cardiovascular devices, with its cleared device designed to facilitate transseptal access to the left atrium. The company achieved its first and latest clearance in 2026, demonstrating active regulatory engagement. The ...

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k260839/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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