

**K250632 Arctx Cool Catheter Set**Oct 30, 2025  
241 days to decisionK250632 · Product code: **PLA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250632/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Thermal Regulation And Gastric Suctioning Device (PLA)
Date received	Mar 3, 2025
Decision date	Oct 30, 2025
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arctx Medical</b>
Location	Raleigh, NC, US
Contact	Don Gurskis
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Domecus Consulting Services, LLC</b>
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250632/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026