

**K240873 TEMBO Embolic System**Dec 16, 2024  
262 days to decisionK240873 · Product code: **KRD** · CardiovascularSource: <https://www.510kdatabase.net/k240873/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Mar 29, 2024
Decision date	Dec 16, 2024
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instylla, Inc.</b>
Location	Waltham, MA, US
Contact	Jennifer Greer
510(k) history	9 submissions · 9 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240873/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026