

K253677 Tembo Embolic SystemDec 15, 2025
24 days to decisionK253677 · Product code: **KRD** · CardiovascularSource: <https://www.510kdatabase.net/k253677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Nov 21, 2025
Decision date	Dec 15, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253677/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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