

K250209 Polyvinyl Alcohol Embolic MicrospheresSep 23, 2025
242 days to decisionK250209 · Product code: **KRD** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jan 24, 2025
Decision date	Sep 23, 2025
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Canyon Medical, Inc.
Location	Nanjing, CN
Contact	Huiqi Jiang
510(k) history	5 submissions · 5 cleared · 2023-2025

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