

**K232934 Sunsphere**May 30, 2024  
253 days to decisionK232934 · Product code: **KRD** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232934/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 20, 2023
Decision date	May 30, 2024
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Yangshun Medical Technology Co.,Ltd</b>
Location	Hangzhou, CN
Contact	Hui Dong
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232934/> 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 13, 2026