

K210562 HRSpheres Narrow-Size Embolic MicrospheresOct 1, 2021
218 days to decisionK210562 · Product code: **KRD** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k210562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Feb 25, 2021
Decision date	Oct 1, 2021
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Hengrui Hongyuan Medical Co., Ltd.
Location	Suzhou, CN
Contact	Qianqian Zhang
510(k) history	2 submissions · 2 cleared · 2021-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210562/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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