

K231554 UniPearls® Embolic MicrospheresNov 14, 2023
168 days to decisionK231554 · Product code: **KRD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k231554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	May 30, 2023
Decision date	Nov 14, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Haowei Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Jinyan Shi
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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