

K252812 UniPearls® Embolic Microspheres

Jul 31, 2026
330 days to decision

K252812 · Product code: **KRD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252812/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 4, 2025
Decision date	Jul 31, 2026
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Haowei Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Jinyan Shi
510(k) history	2 submissions · 2 cleared · 2023-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k252812/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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