

K234123 Easi-Vue® embolic microspheres SystemFeb 13, 2024
47 days to decisionK234123 · Product code: **KRD** · CardiovascularSource: <https://www.510kdatabase.net/k234123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Dec 28, 2023
Decision date	Feb 13, 2024
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abk Biomedical, Inc.
Location	Halifax, CA
Contact	Brandi Woods
510(k) history	2 submissions · 2 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234123/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026