

K250276 Nitinol Enhanced Device (NED)May 15, 2025
104 days to decisionK250276 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k250276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jan 31, 2025
Decision date	May 15, 2025
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Embolization, Inc.
Location	Boulder, CO, US
Contact	James Kasic
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Boulder Biomed, LLC, Db a Boulder IQ Db a Boulder
Contact	Melissa Brookshier

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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