

K250133 HARBOR Occlusion DeviceJul 9, 2025
173 days to decisionK250133 · Product code: **KRD** · CardiovascularSource: <https://www.510kdatabase.net/k250133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jan 17, 2025
Decision date	Jul 9, 2025
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nuvascular, Inc.
Location	Irvine, CA, US
Contact	Meadow Wang
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250133/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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