FDA 510(k) Premarket Notification

K250133 HARBOR Occlusion Device

CLEARED

Jul 9, 2025
173 days to decision

K250133 · Product code: **KRD** · Cardiovascular
Source: 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