FDA 510(k) Premarket Notification

K260635 HARBOR Occlusion Device

CLEARED

Jun 12, 2026
106 days to decision

K260635 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k260635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Feb 26, 2026
Decision date	Jun 12, 2026
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nuvascular, Inc.**
Location	Irvine, CA, US
Contact	Meadow Wang
510(k) history	2 submissions · 2 cleared · 2025-2026