June 12, 2026

Nuvascular, Inc.
Meadow Wang
Director, RA/QA
141 Innovation Dr., Suite 100
Irvine, California 92617

Re: K260635
Trade/Device Name: HARBOR Occlusion Device
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: February 26, 2026
Received: February 26, 2026

Dear Meadow Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2026.06.12 08:28:15 -04'00'

Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260635

Device Name
HARBOR Occlusion Device

Indications for Use *(Describe)*
The HARBOR Occlusion Device is indicated for arterial embolization in the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SUBMITTER

Nuvascular Inc.
141 Innovation Dr. Suite 100, Irvine, CA 92617
Phone: 626-233-6758
Contact Person: Meadow S. Wang
Date Prepared: March 16, 2026

DEVICE

Trade Name of the Device: Harbor Occlusion Device
Common Name: Vascular Embolization Device
Classification Name: Device, Vascular, for promoting embolization
Regulatory Class: Class II, 21 CFR 870.3300
Product Code: KRD

PREDICATE DEVICE

Nuvascular Inc.: HARBOR Occlusion Device (KRD) (K250133)

DEVICE DESCRIPTION

The HARBOR Occlusion Device is a self-expanding braided nitinol arterial embolization implant (Figure 1) supplied with components used for implantation (Figure 2). The Device has a radiopaque marker band attached to the proximal end of the implant. The implant is packaged collapsed within an Introducer sheath and attached to a Delivery System provided within a hoop dispenser.
Device implant sizing and dimensions are specified in Table 1. Based on its size, the device is designed to be used with commercially available microcatheters under fluoroscopy for delivery and implantation in the peripheral vasculature.

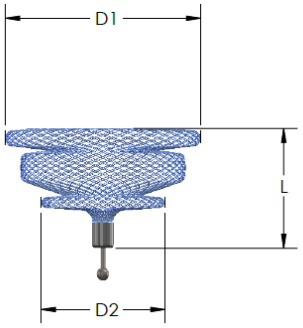

Figure 1 Harbor Occlusion Device – Implant

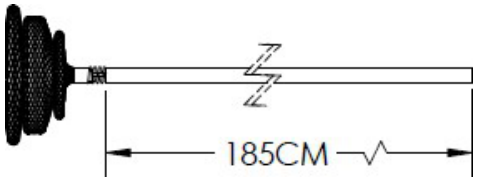

Figure 2 Harbor Occlusion Device – Delivery System

The implant comes in various diameters, ranging from 4.0 to 13.5 mm for Unconstrained OD and 2.0 to 5.4 mm for Unconstrained Length.

The Harbor Occlusion Device will be available in the following with delivery system configurations:

Table 1: HARBOR Occlusion Device Size

Product Model Number	Harbor Occlusion Device OD, Unconstrained, DIM A (mm)	Harbor Occlusion Device Length, Unconstrained, DIM C (mm)	Treatable Vessel Diameter Range (mm)
04-OCCLUDE-020	4.0	2.0	2.0 – 2.5
04-OCCLUDE-025	4.0	2.5	2.0 – 2.5
04-OCCLUDE-030	4.5	2.8	2.5 – 3.0
04-OCCLUDE-035	5.0	3.0	3.0 – 3.5
04-OCCLUDE-040	5.5	3.2	3.5 – 4.0
04-OCCLUDE-045	6.0	3.4	4.0 – 4.5
04-OCCLUDE-050	6.5	3.6	4.5 – 5.0
04-OCCLUDE-055	7.0	3.8	5.0 – 5.5
04-OCCLUDE-060	7.5	4.0	5.5 – 6.0
04-OCCLUDE-065	8.0	4.2	6.0 – 6.5
04-OCCLUDE-070	8.5	4.4	6.5 – 7.0

04-OCCLUDE-080	9.5	4.6	7.0 – 8.0
04-OCCLUDE-090	10.5	4.8	8.0 – 9.0
04-OCCLUDE-100	11.5	5.0	9.0 – 10.0
04-OCCLUDE-110	12.5	5.2	10.0 – 11.0
04-OCCLUDE-120	13.5	5.4	11.0 – 12.0

The implant is delivered through a microcatheter on a delivery system attached to the implant.

The delivery system attached to the Harbor Occlusion Device implant is 185 cm in length and an outer diameter suitable for delivery through commercially available Microcatheters with ID range from 0.0165" to 0.033".

Table 2: Compatible Microcatheters

HARBOR Catalog Number	Microcatheter Description	Inner Diameter (in)	Usable Length (cm)
04-OCCLUDE-020	Terumo Headway Duo Terumo Headway 17 Terumo VIA 17	0.0165 0.017 0.0175	156 150 154
04-OCCLUDE-025	Terumo Headway Duo Terumo Headway 17 Terumo VIA 17	0.0165 0.017 0.0175	156 150 154
04-OCCLUDE-030	Terumo Headway 17 Terumo VIA 17	0.017 0.0175	150 154
04-OCCLUDE-035	Terumo Headway 17 Terumo VIA 17	0.017 0.0175	150 154
04-OCCLUDE-040	Terumo Headway 17 Terumo VIA 17	0.017 0.0175	150 154
04-OCCLUDE-045	Terumo Headway 17 Terumo VIA 17 Terumo Headway 21 Medtronic Phenom 21	0.017 0.0175 0.021 0.021	150 154 156 160
04-OCCLUDE-050	Terumo Headway 17 Terumo VIA 17 Terumo Headway 21 Medtronic Phenom 21	0.017 0.0175 0.021 0.021	150 154 156 160
04-OCCLUDE-055	Terumo Headway 17 Terumo VIA 17 Terumo Headway 21 Medtronic Phenom 21	0.017 0.0175 0.021 0.021	150 154 156 160
04-OCCLUDE-060	Terumo Headway 17 Terumo VIA 17 Terumo Headway 21 Medtronic Phenom 21	0.017 0.0175 0.021 0.021	150 154 156 160
04-OCCLUDE-065	Terumo Headway 27 Terumo VIA 27	0.027 0.027	156 154

	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
04-OCCLUDE-070	Terumo Headway 27	0.027	156
	Terumo VIA 27	0.027	154
	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
04-OCCLUDE-080	Terumo Headway 27	0.027	156
	Terumo VIA 27	0.027	154
	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
04-OCCLUDE-090	Terumo Headway 27	0.027	156
	Terumo VIA 27	0.027	154
	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
04-OCCLUDE-100	Terumo Headway 27	0.027	156
	Terumo VIA 27	0.027	154
	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
	Terumo VIA 33	0.033	133
04-OCCLUDE-110	Terumo Headway 27	0.027	156
	Terumo VIA 27	0.027	154
	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
	Terumo VIA 33	0.033	133
04-OCCLUDE-120	Terumo Headway 27	0.027	156
	Terumo VIA 27	0.027	154
	Terumo PG Pro	0.027	165
	Stryker XT-27	0.027	150
	Medtronic Phenom 27	0.027	160
	Terumo VIA 33	0.033	133

INDICATIONS FOR USE

The Harbor Occlusion Device is indicated for arterial embolization in the peripheral vasculature.

DEVICE Attributes

Table 3 list the attributes of HARBOR Occlusion Device

Table 3 HARBOR Occlusion Device Attributes	
Device Attributes	**Nuvascular Harbor Occlusion Device (Subject Device)**
Device Classification	Class II, KRD, 21 CFR 870.3300
Intended Use/Indications for Use Statement	Indicated for arterial embolization in the peripheral vasculature
Device Function	Embolization in the arterial peripheral vasculature
Anatomical Location	Peripheral Arterial Vasculature
Harbor (Implant)	Self-expanding, Nitinol mesh occlusion device with non-blood contact platinum core to improve radiopacity. The device has a radiopaque marker band at the proximal end and an uncoated Nitinol ball at one end for attaching to the delivery system.
Implant Material	Nitinol
Implant Shape	Single Layer Braid Device Single Lobe with Cylindrical shape
Delivery System Material	Stainless Steel Hypotube with Nitinol Wire
Introducer Sheath	HDPE, High Density Polyethylene
Radiopaque Marker	Platinum Marker Band at the proximal end of the Harbor Occlusion Device
Delivery Method	Delivered through the commercially available Microcatheters with ID range from 0.0165” to 0.033”
Delivery system Length	185 cm
Detachment System	Mechanical Detachment
Materials of Construction for Implant	Nitinol Wire (Main Substances: Nickel: 55-57%, Titanium: 43-45%)
Materials of Construction for Delivery system	Stainless Steel Hypotube with inner Nitinol wire
Marker Bands	Platinum
Packaging	Harbor Occlusion Device includes implant attached to 185 cm long delivery system, loaded in a hoop dispenser
Sterilization Process	Ebeam
Method of Supply	Sterile, single use

COMPARISION OF TECHNOLOGICAL CHARACTERISTICS OF THE HARBOR OCCLUSION DEVICE WITH THE PREDICATE DEVICE

The predicate device for this Special 510(k) submission is the HARBOR Occlusion Device (K250133), which is the submitter's own legally marketed device previously cleared by U.S. Food and Durg Administration under K250133.

The subject device is a shelf-life extension from 6 months to 1 year based on the predicate device. The modification does not affect the intended use or the fundamental scientific technology of the predicate device. The modification was evaluated through the submitter's design control process, including risk analysis and design verification and validation activities.

The subject device is to add additional compatible delivery microcatheters. Adding additional compatible delivery microcatheters does not change the intended use or the fundamental scientific technology of the predicate device. The modification was evaluated through the submitter's design control process, including risk analysis and design verification and validation activities.

Table 1 compares the subject device, HARBOR Occlusion Device, to the predicate device, HARBOR Occlusion Device (K250133).

Table 1 Compares the subject device, HARBOR Occlusion Device, to the predicate device, HARBOR Occlusion Device (K250133)

Device Attributes	**Nuvascular HARBOR Occlusion Device (Subject Device)**	**Nuvascular HARBOR Occlusion Device (Predicate Device) (K250133)**	**Justification for Difference (If Present)**
Device Classification	Class II, KRD, 21 CFR 870.3300	Class II, KRD, 21 CFR 870.3300	Same classification
Intended Use/ Indications for Use Statement	Indicated for arterial embolization in the peripheral vasculature	Indicated for arterial embolization in the peripheral vasculature	Same Intended Use/Indication for Use Statement
Device Function	Arterial embolization in the peripheral vasculature	Arterial embolization in the peripheral vasculature	Same device function
Anatomical Location	Peripheral Arterial Vasculature	Peripheral Arterial Vasculature	Use for the same anatomical location
HARBOR (Implant)	Self-expanding, Nitinol mesh occlusion device with non-blood contact platinum core to improve radiopacity. The device has a radiopaque marker band at the proximal end and an uncoated Nitinol ball at one end for attaching to the delivery system.	Self-expanding, Nitinol mesh occlusion device with non-blood contact platinum core to improve radiopacity. The device has a radiopaque marker band at the proximal end and an uncoated Nitinol ball at one end for attaching to the delivery system.	Same Implant
Product Model Number	04-OCCLUDE-020 04-OCCLUDE-025 04-OCCLUDE-030 04-OCCLUDE-035 04-OCCLUDE-040 04-OCCLUDE-045 04-OCCLUDE-050 04-OCCLUDE-055	04-OCCLUDE-020 04-OCCLUDE-025 04-OCCLUDE-030 04-OCCLUDE-035 04-OCCLUDE-040 04-OCCLUDE-045 04-OCCLUDE-050 04-OCCLUDE-055	Same Product Model Number

	04-OCCLUDE-060 04-OCCLUDE-065 04-OCCLUDE-070 04-OCCLUDE-080 04-OCCLUDE-090 04-OCCLUDE-100 04-OCCLUDE-110 04-OCCLUDE-120	04-OCCLUDE-060 04-OCCLUDE-065 04-OCCLUDE-070 04-OCCLUDE-080 04-OCCLUDE-090 04-OCCLUDE-100 04-OCCLUDE-110 04-OCCLUDE-120	
HARBOR (Implant) OD, Unconstrained	4.0 mm 4.0 mm 4.5 mm 5.0 mm 5.5 mm 6.0 mm 6.5 mm 7.0 mm 7.5 mm 8.0 mm 8.5 mm 9.5 mm 10.5 mm 11.5 mm 12.5 mm 13.5 mm	4.0 mm 4.0 mm 4.5 mm 5.0 mm 5.5 mm 6.0 mm 6.5 mm 7.0 mm 7.5 mm 8.0 mm 8.5 mm 9.5 mm 10.5 mm 11.5 mm 12.5 mm 13.5 mm	The same unconstrained OD
HARBOR (Implant) Unconstrained Length	2.0 mm 2.5 mm 2.8 mm 3.0 mm 3.2 mm 3.4 mm 3.6 mm 3.8 mm 4.0 mm 4.2 mm 4.4 mm 4.6 mm 4.8 mm 5.0 mm 5.2 mm 5.4 mm	2.0 mm 2.5 mm 2.8 mm 3.0 mm 3.2 mm 3.4 mm 3.6 mm 3.8 mm 4.0 mm 4.2 mm 4.4 mm 4.6 mm 4.8 mm 5.0 mm 5.2 mm 5.4 mm	Same, Implant Unconstrained Length
Target Vessel Diameter	2.0 mm-2.5 mm 2.5 mm-3.0 mm 3.0 mm-3.5 mm 3.5 mm-4.0 mm 4.0 mm-4.5 mm 4.5 mm-5.0 mm 5.0 mm-5.5 mm 5.5 mm-6.0 mm 6.0 mm-6.5 mm 6.5 mm-7.0 mm 7.0 mm-8.0 mm 8.0 mm-9.0 mm 9.0 mm-10.0 mm 10.0 mm-11.0 mm 11.0 mm-12.0 mm	2.0 mm-2.5 mm 2.5 mm-3.0 mm 3.0 mm-3.5 mm 3.5 mm-4.0 mm 4.0 mm-4.5 mm 4.5 mm-5.0 mm 5.0 mm-5.5 mm 5.5 mm-6.0 mm 6.0 mm-6.5 mm 6.5 mm-7.0 mm 7.0 mm-8.0 mm 8.0 mm-9.0 mm 9.0 mm-10.0 mm 10.0 mm-11.0 mm 11.0 mm-12.0 mm	Same Target Vessel Diameter Scope.

Implant Shape	Single Layer Braid Device Single Lobe with Cylindrical shape	Single Layer Braid Device Single Lobe with Cylindrical shape	Same Implant Shape
Loading Device Method	Introducer Sheath, HDPE	Introducer Sheath, HDPE	Same Loading Method
Radiopaque Marker Band	Platinum Marker Band at the proximal end of the HARBOR Occlusion Device	Platinum Marker Band at the proximal end of the HARBOR Occlusion Device	Same Radiopaque Marker Band
Compatible with Microcatheter	Delivered and compatible with the commercialized microcatheters from ID 0.0165" to 0.033" See all compatible microcatheters in the proposed IFU.	Delivered and compatible with Terumo Headway 17, 0.017" or Headway 27, 0.027"	To support adding additional compatible microcatheters, supporting data is in below test reports: TR-04-0018 Revision B Design Verification and Validation Test Report TR-04-0027 Revision C, Particulate Test for HARBOR Occlusion Device
Delivery System Length	185 cm	185 cm	Same Delivery System Length
Detachment System	Mechanical Detachment	Mechanical Detachment	Same Mechanical Detachment Method
Device Material			
Materials of Construction for Implant	Nitinol Wire (Main Substances: Nickel: 55-57%, Titanium: 43-45%)	Nitinol Wire (Main Substances: Nickel: 55-57%, Titanium: 43-45%)	Same material of Implant
Materials of Construction for Delivery System	Stainless Steel Hypotube with inner Nitinol Delivery Wire	Stainless Steel Hypotube with inner Nitinol Delivery Wire	Same material of Delivery System
Marker Bands	Platinum	Platinum	Same material of Marker Bands
Other Attributes			
Packaging Configuration	Harbor Occlusion Device includes implant attached to 185 cm long delivery system, loaded in a hoop dispenser	Harbor Occlusion Device includes implant attached to 185 cm long delivery system, loaded in a hoop dispenser	Same Packaging Configuration
Sterilization Process	Ebeam	Ebeam	Same Sterilization Method
Method of Supply	Sterile, single use	Sterile, single use	Same Supply Method
Shelf-Life	1 Year	6 Months	TR-04-0023 Revision B is for 1 year Shelf-Life Study Report

SUMMARY OF HARBOR OCCLUSION DEVICE PERFORMANCE TEST

The data presented in this submission demonstrate that the subjective device, HARBOR Occlusion Device has successfully completed the following performance testing activities and performs comparably to the predicate device, HARBOR Occlusion Device(K250133):

- Bench performance testing was conducted to evaluate compatibility with additional commercially available microcatheters listed in the proposed IFU. The test results demonstrated that the device maintains acceptable functional performance with the proposed compatible microcatheters.
- Shelf-life testing was conducted to support an extension of the device shelf life to 1 year. The results demonstrated that the device continues to meet applicable performance specifications following the requirements of accelerated aging and design specifications.

SUMMARY OF SUBSTANTIAL EQUIVALENCE:

The data presented in this submission demonstrates the technological similarity and equivalency of the subject HARBOR Occlusion Device when compared with the predicate device, HARBOR Occlusion Device (K250133).

The Subject device,

- has the same intended use as the predicate device,
- has the same indication for use as the predicate device,
- uses the same operating principle as the predicate device,
- uses the same materials as the predicate device,
- incorporates the same design and construction as the predicate device,
- has the same unconstrained OD range as the predicate device,
- has the same unconstrained Length range as the predicate device,
- has the same packaging configuration and method as the predicate device,
- has the same sterilization method as the predicate device.

In summary, the subject HARBOR Occlusion Device described in this submission is substantially equivalent to the predicate device, HARBOR Occlusion Device (K250133).