July 9, 2025

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

Re: K250133
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: June 9, 2025
Received: June 9, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Misti L. Malone -S

Misti Malone, PhD
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)*
K250133

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:
June 8, 2025

DEVICE

Trade Name of the Device: Harbor Occlusion Device
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

AGA Medical Corporation (was acquired by Abbott): AMPLATZER® Vascular Plug 4, Arterial Embolization Device (KRD) (K113658) (primary predicate)

AGA Medical Corporation (was acquired by Abbott): AMPLATZER® Vascular Plug, Arterial Embolization Device (KRD) (K031810)

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 (Table 2) under fluoroscopy for delivery and implantation in the peripheral vasculature.

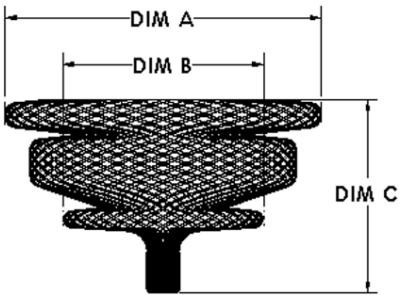

Figure 1 Harbor Occlusion Device – Implant

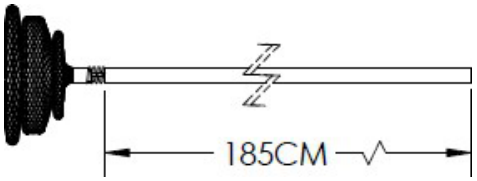

Figure 2. Harbor Occlusion Device – Delivery System

The implant comes in various diameters ranging from 4.0 to 13.5 mm Unconstrained OD and 2.0 to 5.4 mm Unconstrained Length. The Harbor Occlusion Device will be available in the following with delivery system configurations:

Table 1: 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)	Compatible Microcatheter (Inch)
04-OCCLUDE-020	4.0	2.5	2.0 – 2.5	0.017
04-OCCLUDE-025	4.0	2.5	2.0 – 2.5	0.017
04-OCCLUDE-030	4.5	2.8	2.5 – 3.0	0.017
04-OCCLUDE-035	5.0	3.0	3.0 – 3.5	0.017
04-OCCLUDE-040	5.5	3.2	3.5 – 4.0	0.017
04-OCCLUDE-045	6.0	3.4	4.0 – 4.5	0.017
04-OCCLUDE-050	6.5	3.6	4.5 – 5.0	0.017
04-OCCLUDE-055	7.0	3.8	5.0 – 5.5	0.017
04-OCCLUDE-060	7.5	4.0	5.5 – 6.0	0.017
04-OCCLUDE-065	8.0	4.2	6.0 – 6.5	0.017
04-OCCLUDE-070	8.5	4.4	6.5 – 7.0	0.027
04-OCCLUDE-080	9.5	4.6	7.0 – 8.0	0.027
04-OCCLUDE-090	10.5	4.8	8.0 – 9.0	0.027
04-OCCLUDE-100	11.5	5.0	9.0 – 10.0	0.027
04-OCCLUDE-110	12.5	5.2	10.0 – 11.0	0.027
04-OCCLUDE-120	13.5	5.4	11.0 – 12.0	0.027

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 Microcatheter- Terumo Headway 17 with 0.017" ID Microcatheter or Terumo Headway 27 with 0.027" ID Microcatheter.

Table 2 Compatible with the available Commercial Microcatheter			
Description	Catalog Number	Inner Diameter (In)	Usable Length (cm)
Terumo Headway 17	MC172150SX	0.017	150
Terumo Headway 27	MC172156S	0.027	156

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 and compatible with Terumo Headway 17, 0.017" or Headway 27, 0.027" microcatheter Terumo Headway 17 MC172150SX: Inner Diameter (in): 0.017 Usable Length (cm) 150 Terumo Headway 27 MC272156S: Inner Diameter (in): 0.027 Usable Length (cm): 156
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 method of application of the Harbor Occlusion Device is the same as the predicate device, AMPLATZER Vascular Plug 4, Arterial Embolization Device (KRD) (K113658) and AMPLATZER Vascular Plug, Arterial Embolization Device (KRD) (K031810). They both utilize the same principle of operation to be delivered to a select target site for the vessel and embolic used. They are both available in a range of diameters to permit the selection of appropriate sizes for target vessel embolization. Accurate placement of the Harbor Occlusion Device is conducted with visualization using radiographic (fluoroscopy) imaging.

Table 4 compares the subject device, HARBOR Occlusion Device, and the predicate.

Table 4: Comparison of Technological Characteristics with the Predicate Device

Device Attributes	**Nuvascular HARBOR Occlusion Device (Subject Device)**	**Abbott AMPLATZER® Vascular Plug 4 (Primary Predicate Device) (K113658)**	**Abbott AMPLATZER® Vascular Plug (Predicate Device) (K031810)**	**Justification for Difference (If Present)**
Device Classification	Class II, KRD, 21 CFR 870.3300	Class II, KRD, 21 CFR 870.3300	Class II, KRD, 21 CFR 870.3300	Same, Identical device classification
Intended Use/ Indications for Use Statement	Indicated for arterial embolization in the peripheral vasculature	Indicated for arterial and venous embolization in the peripheral vasculature	Indicated for arterial and venous embolization in the peripheral vasculature	Same Intended Use/Indication for Use Statement, the intended use of the subject device is narrower than the predicate device
	Principle of Operation/Fundamental Scientific Technology			
Device Function	Arterial embolization in the peripheral vasculature	Embolization in the peripheral vasculature	Embolization in the peripheral vasculature	Same function, subject device function is narrower than the predicate device
Anatomical Location	Peripheral Arterial Vasculature	Peripheral Vasculature including arterial and venous	Peripheral Vasculature including arterial and venous	Same, the anatomical location of subject device is narrower than the predicate device
	Device Design			

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. The device has a radiopaque marker band at each end and a coated stainless steel micro screw attachment at one end for attaching to the delivery system.	Self-expanding, Nitinol mesh occlusion device. The device has a radiopaque marker band at each end and a micro screw attachment at one end for attaching to the delivery system.	Similar device design. The results of comparative bench testing, physician usability study, histopathology, biocompatibility testing, and animal study establish the substantial equivalency of the subject device with the predicate device.
Harbor OD, Unconstrained	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 5.0 mm 6.0 mm 7.0 mm 8.0 mm	4.0 mm 6.0 mm 8.0 mm 10.0 mm 12.0 mm 14.0 mm 16.0 mm	Same, the OD range of the subject device is narrower than the predicate device.
Harbor Unconstrained Length	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	10.0 mm 10.5 mm 11.0 mm	7.0 mm 8.0 mm	The range of Unconstrained Length for the subject device is similar to the predicated device The subject device has a smaller unconstrained length compared to the predicate device. Test data show the radial force met the radial force acceptance criteria, the simulated use test shows the subject device functions are the same as the predicate device, and the animal test met acceptance criteria. The subject device is

		12.5 mm 13.5 mm		substantially equivalent to the predicate device.
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	2.5 mm-3.0 mm 3.5 mm-4.0 mm 4.0 mm-4.5 mm 4.5 mm-5.5 mm 5.5 mm-6.0 mm	2.5 mm-3.0 mm 4.0 mm-4.5 mm 5.5 mm-6.0 mm 6.5 mm-7.5 mm 8.0 mm-9.0 mm 9.5 mm-11.0 mm 10.5 mm-12.5 mm	The range of the treated target vessel diameter for the subject device is similar to the predicate device. The subject device treats vessels 2.0 mm to 12.0 mm compared to 2.5 mm to 12.5 mm for the predicate device. 90-day GLP animal data, histopathology, and bench testing show that the subject device can treat 2.0 mm vessels. Test data show the radial force met the radial force acceptance criteria, the simulated use test shows the subject device functions are the same as the predicate device, and the animal test met acceptance criteria. The subject device is substantially equivalent to the predicate device.
Implant Shape	Single Layer Braid Device Single Lobe with Cylindrical shape	Single Layer Braid Device Double-Lobed with low-profile embolization	Single Layer Braid Device Single Lobe with Cylindrical shape	Same single layer braid device with similar shape
Delivery System Material	Stainless Steel Hypotube with Nitinol Wire	PTFE-coated Stainless Steel Wire Coil with Nitinol Core	Nitinol	Similar, the biocompatibility test results of the delivery system show the subject device met the acceptance criteria of ISO 10993.

Loading Device Method	Introducer Sheath, HDPE	Loader, PTFE	Loader, PTFE	Similar, the biocompatibility test results of the delivery system show the subject device met the acceptance criteria of ISO 10993
Radiopaque Marker	Platinum Marker Band at the proximal end of the Harbor Occlusion Device	Platinum Marker Bands at each end of the plug	Platinum Marker Bands at each end of the plug	Same material with the same principle
Delivery Method	Delivered and compatible with Terumo Headway 17, 0.017" or Headway 27, 0.027" Microcatheter Terumo Headway 17 MC172150SX: Inner Diameter (in): 0.017 Usable Length (cm): 150 Terumo Headway 27 MC272156S: Inner Diameter (in): 0.027 Usable Length (cm): 156	Delivered utilizing a Diagnostic Catheter 0.038" meeting the minimum internal diameter Catheter Size: 5F with length ≤125cm 4F with length ≤100cm	Delivered utilizing a Diagnostic Catheter 0.056", 0.066", and 0.087" meeting the minimum internal diameter Compatible with Guide Catheter size: Vessel size vs Minimum Guide Cather Size 2.5mm-6.0mm, ≥ 0.066" 6.5 mm-9.0mm, ≥ 0.087" 9.5 mm-12.5mm, ≥ 0.11" Catheter Length: ≤100cm	Similar delivery method. The Harbor Occlusion Device is designed to be delivered through a smaller ID (0.017" or 0.027" inner diameter) microcatheter. The results of bench testing and physician usability study establish the substantial equivalence of the subject device has substantially equivalent function as the predicate device
Delivery system Length	185 cm	155 cm	135 cm	The Harbor Occlusion Device is designed to be delivered through a longer-length delivery system The results of bench testing and physician usability study establish the substantial equivalence of subject device to the predicate device
Detachment System	Mechanical Detachment	Mechanical Detachment	Mechanical Detachment	Same principle

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%)	Nitinol Wire (Main Substances: Nickel: 55-57%, Titanium: 43-45%)	Same
Materials of Construction for Delivery system	Stainless Steel Hypotube with inner Nitinol Delivery wire	PTFE-coated Stainless Steel wire coil with inner Nitinol wire	Nitinol wire	Similar device material construction. The subject device has stainless steel Hypotube with inner Nitinol Delivery wire without PTFE- Coating The materials used for the Harbor Vessel Occlusion Device met the acceptance criteria of ISO 10993 for delivery system.
Marker Bands	Platinum	Platinum	Platinum	Same
Micro Screw	N/A	Stainless Steel	Stainless Steel	The subject device has no micro screw
Other Attributes				
Packaging	Harbor Occlusion Device includes implant attached to 185 cm long delivery system, loaded in a hoop dispenser	The device is shipped attached to a 155 cm delivery system in a hoop dispenser and is preloaded in a loader. A plastic vise is also included and may be attached to the delivery system to facilitate device detachment	The device is shipped attached to a 135 cm. delivery system in a hoop dispenser and is preloaded in a loader. A plastic vise is also included and may be attached to the delivery system to facilitate device detachment	Similar The packaging validation result for the subject device shows the packaging integrity can meet the requirements per ASTM D4169, ASTM D4332, ASTM F88/F88M, ASTM F2096.
Sterilization Process	Ebeam	EtO (Ethylene Oxide)	EtO (Ethylene Oxide)	The sterilization validation result shows Harbor Occlusion Device met SAL of 10^{-6}
Method of Supply	Sterile, single use	Sterile, single use	Sterile, single use	Same

SUMMARY OF HARBOR OCCLUSION DEVICE PERFOMANCE TESTING:

1. Bench Test

Table 5: Verification and Test Summary	
Pre-clinical Testing	Result
Implant, Biocompatibility Testing (ISO 10993-1) - Medical Device Chemical Characterization and Extractables and Leachable for Compatibility of Materials (ISO 10993-18) - Implant Hemolysis Test - Implant Complement Activation Test - Toxicological Risk Assessment (ISO 10993- 17) - Cytotoxicity (ISO 10993-5) ➢ L929 MEM Elution Cytotoxicity Assay - Sensitization (ISO 10993-10) ➢ Kligman Maximization Sensitization in Guinea pigs with two extracts - Irritation (ISO 10993-23) ➢ Irritation/Intracutaneous Injection Reactivity - Pyrogenicity (ISO 10993-11) ➢ Material Mediated Rabbit Pyrogen - Biocompatibility Evaluation Report (ISO10993-1)	In accordance with ISO 10993
Delivery system with Introducer Sheath, Biocompatibility testing (ISO 10993-1) - Cytotoxicity (ISO 10993-5) ➢ L929 MEM Elution Cytotoxicity Assay - Sensitization (ISO 10993-10) ➢ Kligman Maximization Sensitization in Guinea pigs with two extracts - Irritation (ISO 10993-23) ➢ Irritation/Intracutaneous Injection Reactivity - Systemic Toxicity (ISO 10993-11) ➢ Acute Systemic Injection with two extracts - Pyrogenicity (ISO 10993-11) ➢ Material Mediated Rabbit Pyrogen - Hemocompatibility (ISO 10993-4) ➢ ASTM Hemolysis Complete, Indirect Contact	In accordance with ISO 10993

Preclinical Testing including Mechanical, Visual, and Bench Testing – Visual/Dimension Inspection – Simulated Use ➢ Preparation/Flush ➢ Introduction ➢ Tracking ➢ Advancement ➢ Kink Resistance ➢ Flexibility ➢ Microcatheter Compatibility ➢ Deployment ➢ Retraction ➢ Detachment ➢ Migration Resistance ➢ Overall Performance – Radial Force – Implant Tensile Strength – Joint Tensile Strength – Nickel Ion Release – Corrosion Resistance – Magnetic Resonance (MR) Testing – Radiopacity – Occlusion Time – Shelf-Life Study (Products/Packaging) – Pyrogenicity ➢ Sterility	Pass
Packaging validation (Products/Packaging)	Pass
Sterilization validation (Sterilization)	Pass
Shelf-Life Study (Products/Packaging)	Pass

2. GLP Animal Study

Table 6: GLP Animal Study Summary	
Pre-clinical Testing	Result
Animal testing – device compared to predicate device (Acute, 30 days and 90 days) – Ease of delivery (friction and tortuosity) – Acute Complications – Recanalization of the vessels/durability of occlusion – Local and systemic foreign body reactions – Device migration – Effectiveness	Pass

SUMMARY OF SUBSTANTIAL EQUIVALENCE:

The data presented in this submission demonstrates the technological similarity and equivalency of the Harbor Occlusion Device when compared with the predicate device, AMPLATZER® Vascular Plug 4, Arterial Embolization Device (KRD) (K113658) and AMPLATZER® Vascular Plug, Arterial Embolization Device (KRD) (K031810).

The Subject device,

- has the same intended use to the predicate devices,
- has the intended use is narrower than the predicate devices,
- uses same operating principle as the predicate devices,
- uses similar materials, the types of material in subject device are less than the predicate devices,
- incorporates similar basic design and construction to the predicate devices,
- uses a similar packaging method to the predicate devices,
- has similar unconstrained OD range to the predicate devices,
- has similar unconstrained Length ranges to the predicate devices

In summary, the Harbor Occlusion Device described in this submission is substantially equivalent to the predicate devices.