510(K) SUMMARY

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Date of Summary Prepared:	April 13, 2019
Name of Device:	Dr. Amplatz Micro Plug
Common/Usual Name:	Vascular Device for promoting embolization
Classification Name:	Vascular embolization device
Classification:	Product Code: KRD Regulation Number: 21 CFR 870.3300 Class: II
Predicate and Reference Device(s):	<u>Predicate:</u> Amplatzer ® Vascular Plug (AVP 1) - K031810 <u>Reference:</u> Amplatzer® Vascular Plug 4 (AVP 4) - K113658 Amplatzer ® Vascular Plug 2 (AVP 2) - K071125

Device Description: The Dr. Amplatz Micro Plug includes the Micro Plug Device which is a self-expanding braided Nitinol vascular occlusion implant that is supplied with components used for implantation.

The Micro Plug Device has been designed with a material, size, configuration and shape that allows introduction through a catheter for the occlusion of blood vessels in the peripheral vasculature. The Micro Plug Devices are provided in four different diameters (3 mm - 6 mm) to treat different sized blood vessels in the peripheral vasculature. The Micro Plug Device has radiopaque marker bands attached to each end and a screw attachment for connection to a Delivery Wire. The Micro Plug Device is packaged collapsed within a Loader and attached to a 180 cm Delivery Wire that is provided within a hoop dispenser.

The delivery system includes a 125 cm Delivery Catheter that is provided within a hoop dispenser for delivery and implantation of the Device; the Delivery Catheter contains a standard luer hub adapter at the proximal end and a single radiopaque marker band at the distal end. The Delivery Catheter is hydrophilic coated. Tuohy Borst Valves are provided for flushing; a Torque Device is provided for releasing the Device.

The Dr. Amplatz Micro Plug is designed to be used under fluoroscopy for delivery and implantation in the peripheral vasculature by physicians trained in vascular embolization.

Indication for Use: The Dr. Amplatz Micro Plug is indicated for arterial embolization in the peripheral vasculature.

Comparison to Predicate Devices: The Dr. Amplatz Micro Plug is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the predicate device.

A comparison of the technological characteristics is summarized in the table below.

Device Characteristic	New Device: Dr. Amplatz Micro Plug	Predicate Device: Amplatzer ® Vascular Plug - K031810
Product Code	KRD	Same
Intended Use/Indications for Use	indicated for arterial embolization in the peripheral vasculature	indicated for arterial and venous embolizations in the peripheral vasculature
Device Components	• Micro Plug Device • Delivery Catheter • Delivery Wire • Loader • Torque Device • Tuohy Borst Valve Identical component list to reference device K113658	• Plug • Delivery Wire • Loader

Device Characteristic	**New Device: Dr. Amplatz Micro Plug**	**Predicate Device: Amplatzer ® Vascular Plug - K031810**
Design and Dimensions	Micro Plug Device Device contains 3 flat lobes with 2 constrained central regions. Reference device K0171125 contains 2 flat lobes and a central lobe with 2 constrained central regions. Reference device K071125 diameter range (3 mm – 22 mm) is inclusive of the subject device diameter range. Device Diameter x Device Length 3 mm x 2.5 mm 4 mm x 2.5 mm 5 mm x 2.5 mm 6 mm x 2.5 mm	Plug Device Device is a single lobe – generally barrel or tubular shaped with one flat and one tucked end. Device Diameter x Device Length 4 mm x 7 mm 6 mm x 7 mm 8 mm x 7 mm 10 mm x 7 mm 12 mm x 8 mm 14mm x 8 mm 16 mm x 8 mm
	Delivery Catheter Outer diameter 2.9 F Inner diameter .028 in Length 125 cm	No delivery catheter is included in the predicate set. Introduction through 0.056 –0.088-inch inner diameter catheters is recommended.
Materials	Micro Plug Device Nitinol Platinum-iridium Stainless Steel	Plug Same
	Delivery System Loader Nylon LDPE PTFE Delivery Wire Nitinol Stainless steel Delivery Catheter Nylon Pebax Stainless steel braid PTFE Grilamed Platinum/Iridium Hydrophilic coating	Delivery System Loader PTFE Delivery Wire Nitinol Stainless steel Delivery Catheter N/A (Commercially available 0.056 – 0.088-inch inner diameter guide catheters)
Sterilization	Sterile/Ethylene Oxide SAL 10-6	Same
Shelf Life	Three Year	Same
Disposable Single Use	Yes	Same

Performance Data: Safety and performance evaluations used to establish substantial equivalence of the subject device to the predicate device include the following:

- Simulated Use
  - Flushing
  - Advancement
  - Deployment Force
  - Apposition
  - Recapture
  - Release
- Tensile Strength
- Radial Force
- Torque to Failure
- Kink to Failure
- Burst
- Fatigue
- Leak Test
- MRI Compatibility
  - Interactions
  - Heating
  - Artifacts
- Corrosion
- Nickel Leaching
- Packaging
  - Seal Peel Strength
  - Visual
  - Bubble Leak Test
- Sterilization
  - Fractional Cycle
  - Half Cycle
  - Full Cycle
- Biocompatibility
  - Toxicological Risk Assessment
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Systemic Toxicity
  - Implantation
  - Hemocompatibility
  - Complement Activation
  - Pyrogenicity

- Shelf Life
- Chronic GLP Animal Study
    - Acute performance
    - Chronic performance
    - Tissue response

Clinical testing was not required for the determination of substantial equivalence.

Conclusion: Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications and intended use. Based upon the same intended use and principle of operation, technology, and nonclinical testing it is concluded that the Dr. Amplatz Micro Plug is substantially equivalent to the predicate device.