510(k) Summary

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510(k) SPONSOR: EMBA Medical Limited
3451 Commerce Parkway
Miramar, FL 33025
Phone Number: 954-874-1016

TRADE NAME: EMBA™ HOURGLASS™ Peripheral Embolization Device (PED)

COMMON NAME: Vascular Embolization Device

Product	Regulation and Description	Product Code	Device	Device Class
Peripheral Embolization Device (PED)	21 CFR 870.3300 Vascular Embolization Device	KRD	Vascular Embolization Device	II

PREDICATE DEVICES:
Reverse Medical® MVP® Micro Vascular Plug System (K141313)
Amplatzer® Vascular Plug 4 (K113658)

DEVICE DESCRIPTION:
The EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) consists of a covered, implantable, self-expanding structure (Embolic Device) preloaded in a catheter-based Delivery System. The Embolic Device is intended to be deployed to the target site in the vasculature under fluoroscopic guidance. The product is shipped sterile and labeled for single use only.

The configuration of the EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) is listed below.

Reference Number	Embolic Device Diameter (mm)	Embolic Device Length (mm)	Embolic Device Maximum Covered Length (mm)
PEP-001	10	20	10

INDICATIONS FOR USE:
The EMBA Peripheral Embolization Device (PED) is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature in 6-8mm blood vessels. The device is not indicated for use in blood vessels subject to repetitive motion, such as extremity or pulmonary vessels.

CONTRAINDICATIONS
The device should not be implanted in vessels < 6 mm due to risk of vessel perforation or device fracture.

The device is not indicated for use in blood vessels subject to repetitive motion, such as extremity or pulmonary vessels due to risk of device fracture.

BASIS FOR SUBSTANTIAL EQUIVALENCE:
The EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) and the predicate devices, Reverse Medical® MVP® Micro Vascular Plug System and Amplatzer® Vascular Plug 4 are intended for embolization/obstruction of blood flow in the peripheral vasculature – arterial and venous. Compared to the predicate devices, the subject device is not indicated for use in blood vessels < 6 mm or subject to repetitive motion; however, these differences do not introduce a new intended use. Additionally, the combination of device labeling and totality of data support that the EMBA Hourglass does not raise new questions of safety and effectiveness.

The operating principle of the EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) and the predicate devices, Reverse Medical® MVP® Micro Vascular Plug System, and Amplatzer® Vascular Plug 4 are equivalent. All the devices are delivered through a Delivery System that is introduced into the vasculature using standard techniques. The Delivery System is advanced to the site of interest by the physician using fluoroscopic guidance. Once in position, the Embolic Device is delivered by manipulating the Delivery System to mechanically release the Embolic Device. The Amplatzer® Vascular Plug 4 and Reverse Medical® MVP® Micro Vascular Plug System are mounted on a pusher and tracked through a guide catheter to the desired location. The EMBA™ HOURGLASS™ Peripheral Embolization Device is mounted on a pusher, inside an outer body, which is tracked to the desired location. The Amplatzer® Vascular Plug 4 and Reverse Medical® MVP® Micro Vascular Plug System are deployed by rotating the delivery wire to unscrew the proximal end of the embolic device from the wire. The EMBA™ HOURGLASS™ Peripheral Embolization Device is released by retracting the outer body until the embolic device is exposed, thus allowing the proximal portion of the device to expand, releasing the device from the interlock mechanism. Although there are technological differences in the delivery system and modes of detachment, these differences do not raise any different questions of safety and effectiveness. All of the Embolic Devices consist of a self-expanding material which, when deployed, expand to obstruct the blood flow in the vessel thus triggering the clotting cascade.

The EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) and the predicate devices, Reverse Medical® MVP® Micro Vascular Plug System, and Amplatzer® Vascular Plug 4 have similar technological characteristics and materials of construction. The Reverse Medical® MVP® Micro Vascular Plug System Embolic Device is laser cut nitinol in an oblong shape tapering at each end. The device includes a polymer covering. The Amplatzer® Vascular Plug 4 is a braided wire construction in a multi-lobed shape. The EMBA™ HOURGLASS™

Peripheral Embolization Device (PED) is a laser cut nitinol in a multi-lobed or hourglass shape including a polymer covering. These characteristics are present in the other predicate devices. Design features of the embolic device of the EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) and the predicate devices are very similar and are considered substantially equivalent: Delivery System length, system compatibility, Embolic Device shape, and Embolic Device size, Embolic Device materials of construction, and indicated vessel sizes. Although there are slight technological differences in the embolic device designs, these differences do not raise any different questions of safety and effectiveness.

The subject device, EMBA™ HOURGLASS™ Peripheral Embolization Device (PED), passed appropriate ISO 10993 testing to demonstrate biocompatibility.

The subject device, EMBA™ HOURGLASS™ Peripheral Embolization Device (PED), and the cited predicate devices are provided packaged sterile and all of the devices are terminally sterilized by ethylene oxide (EtO).

Comparative performance testing was conducted to demonstrate that the technological differences the EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) and the predicate devices do not raise concerns of substantial equivalence. Testing was conducted in accordance with the FDA guidance document of "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." Testing conducted consisted of Kink Radius, Trackability, Partial Deployment and Retraction, Deployment Accuracy, Chronic Outward Force, Embolic Device Length and Diameter, Foreshortening, Contrast Flow, Migration Resistance, Occlusion Effectiveness, MR Compatibility, Corrosion, Fatigue Testing, Delivery System Integrity, Shelf Life, and Animal Testing.

Human Use Clinical Testing has been conducted on the EMBA™ HOURGLASS™ Peripheral Embolization Device (PED) (n=51) to evaluate safety and effectiveness endpoints.

CONCLUSIONS:

Review of the in-vitro and in-vivo performance testing as well as the comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility demonstrate that the subject device, EMBA™ HOURGLASS™ Peripheral Embolization Device (PED), is substantially equivalent to the cited predicate devices, Reverse Medical® MVP® Micro Vascular Plug System **(**K141313) and Amplatzer® Vascular Plug 4 (K113658). Any differences between the subject and predicate devices do not raise different questions of safety and effectiveness.