510(k) Summary for MegaVac Mechanical Thrombectomy System

a) General Information

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Summary Preparation Date: July 11, 2017

b) Names

Trade Name: MegaVac Mechanical Thrombectomy System

Common Name: Percutaneous Catheter

Classification Name: Embolectomy Catheter

Product Code: DXE

Regulatory Classification: 21 CFR 870.5150

c) Predicate Device

- Genesis Medical Interventional™ F.A.S.T. ™ (Facilitated Aspiration/Suction Thrombectomy) System (K040010)
- F.A.S.T. SED (Self-Expanding Device) and CXD (Controlled Expansion Device) System (K092623)

d) Product Description

The MegaVac Mechanical Thrombectomy System consists of two single-use devices, the MegaVac Catheter with SafeSeal technology and a ThromboWire clot retractor, for intravascular mechanical thrombectomy, occlusion, aspiration and embolectomy. The MegaVac Catheter with SafeSeal technology utilizes a silicone coated nitinol braided funnel that expands to occlude antegrade blood flow proximal to the target work zone creating a static environment in which to perform the intervention, while also centering and securing the catheter tip position within the vessel. The MegaVac catheter's large-mouth funnel and inner diameter allows for strong aspiration while easily being able to pass the ThromboWire and other lesion disruptive or therapeutic devices through it. The

ThromboWire consists of a nitinol embolectomy element that when expanded by the proximal actuation handle can serve to gather and pull matter towards and through the MegaVac catheter during aspiration.

e) Indications for Use

The MegaVac Mechanical Thrombectomy System is indicated for:
- The non-surgical removal of emboli and thrombi from blood vessels.
- The non-surgical removal of thrombi from synthetic grafts.
- Use in temporary blood vessel/graft occlusion.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft
- Catheter placement over a guidewire

f) Rationale for Substantial Equivalence

The MegaVac Mechanical Thrombectomy System and the predicates share the same or similar intended use and technological characteristics and therefore are substantially equivalent.

A comparison of the similarities and differences of the technological characteristics between the new device and the predicates is shown below.

	K171493		K092623	K040010	
	MegaVac Mechanical Thrombectomy System		F.A.S.T. Controlled Expanding Device (CXD)	Genesis Medical Interventional F.A.S.T. System	
Device Component	MegaVac Catheter	ThromboWire (Clot Retractor)	Expanding Basket Thrombectomy Guidewire	Funnel Sheath catheter	Expanding Basket Thrombectomy Guidewire
Basket or Funnel Composition	Polymer coated woven nitinol	Woven nitinol	Woven nitinol	Polymer coated woven nitinol	Woven nitinol
Material	Silicone coated nitinol braided funnel	Nitinol	Nitinol	Silicone coated nitinol braided funnel	Nitinol
Device Profile Dimensions	Up to 9 Fr	.5mm – 1.5mm	0.46mm	Up to 9 Fr	0.914mm (Typical)
Device Lengths	Up to 300cm	Up to 300cm	195cm	Up to 300cm	Up to 300cm
Deployed Diameter	2 – 12mm	2 – 9mm	5.5mm	2 – 12mm	2 – 9mm
Deployment Mechanism	Operator controlled – linear actuation	Operator controlled – linear actuation	Operator controlled – rotational knob	Operator controlled – linear actuation	Operator controlled – linear actuation
Guidewire compatibility	Up to 0.044" OD	N/A	N/A	Up to 0.044" OD	N/A

g) Safety and Effectiveness Information

The MegaVac system is substantially equivalent to the predicate devices regarding its similar intended use, design, function, materials and sterilization method. In accordance

with Capture Vascular's risk analysis and according to international standards, verification testing was conducted on the MegaVac Mechanical Thrombectomy System. A summary of the verification testing conducted on the MegaVac Mechanical Thrombectomy is described below.

Summary of Testing:
Device evaluation consisted of *in vitro* testing and supports the substantial equivalence of the MegaVac Thrombectomy system to the predicate device. All data met the acceptance criteria and fell within pre-determined product specifications and industry standard requirements. The following is a list of tests that were performed:

- **Functional, Dimensional and Mechanical Testing**
  - Occlusion
  - Aspiration
  - Trackability over guidewire
  - Retraction
  - Handle stroke
  - Leakage
  - Tensile
  - Diameters, length
  - Component compatibility (obturator/Thrombowire)

- **Biocompatibility Testing:**
  In accordance with 10993-1 for devices categorized as an "external communicating device in contact with circulating blood with limited exposure time (<24 hours)."

- **Sterilization Testing:**
  A sterilization assessment was conducted in accordance with ANSI/AAMI/ISO 11135.

- **Transportation and Shelf Life Testing:**
  Ship testing was conducted in accordance with ASTM D4169. Shelf life testing was conducted in accordance with ASTM F1980-07.

- **Summary of Pre-Clinical and Clinical Data:**
  No Clinical Data was generated to establish substantial equivalence. Bench data and pre-clinical data are considered adequate to support a determination of substantial equivalence.

h) Conclusion

As described in this 510(k) Summary, the MegaVac Mechanical Thrombectomy System is substantially equivalent to the Genesis Medical Interventional™ F.A.S.T. ™ (Facilitated Aspiration/Suction Thrombectomy) System based on a comparison of intended uses and the results of in-vitro testing.