



Food and Drug Administration  
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August 31, 2016

MicroVention, Inc.  
Ms. Sapna Singh, MS, RAC  
Regulatory Affairs Project Manager  
1311 Valencia Avenue  
Tustin, California 92780

Re: K161367  
Trade/Device Name: HydroCoil<sup>®</sup> Embolic System (HES)  
Regulation Number: 21 CFR 882.5950  
Regulation Name: Neurovascular Embolization Device  
Regulatory Class: Class II  
Product Code: HCG, KRD  
Dated: July 28, 2016  
Received: August 4, 2016

Dear Ms. Singh:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Michael J. Hoffmann -A**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K161367

Device Name

HydroCoil® Embolic System (HES)

Indications for Use (Describe)

The HydroCoil Embolic System (HES) are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) SUMMARY

This 510(k) summary for the HydroCoil® Embolic System (HES) – HydroFrame® 10 is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendations outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, dated 28 July, 2014.

### SUBMITTER [807.92(a)(1)]

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Date Prepared: May 16, 2016

### DEVICE [807.92(a)(2)]

Name of Device: HydroCoil Embolic System (HES)  
Common or Usual Name: HydroCoils  
Classification Name: Neurovascular Embolization Device  
Product Code: HCG, KR D  
Regulatory Class: Class II  
Submission Type: Special 510(K)  
Regulation Number: 21 CFR 882.5950  
Reviewing Product Branch: Division of Neurological and Physical Medicine Devices  
(Office of Device Evaluation, CDRH)

### PREDICATE DEVICE [807.92(a)(3)]

HydroFrame® 10 (K090357, K100454 and K103758)

### DEVICE DESCRIPTION [807.92(a)(4)]

The HydroFrame coils in the HydroCoil Embolic System (HES) consist of implant coil made of platinum alloy with inner hydrogel core.

The coils are designed in 3D spherical structure in various loop sizes and lengths. The coil is

attached to V-Trak™ or V-Trak™ Advanced Delivery Pusher via polyolefin elastomer filament. The Delivery Pusher is a variable stiffness stainless steel hypotube with platinum and stainless steel coils at the distal end. The proximal end of the Delivery Pusher is inserted into a hand held battery powered V-Grip™ Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment.

**INDICATIONS FOR USE [807.92(a)(5)]**

The HydroCoil Embolic System (HES) are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]**

The **Table I** compares the technological characteristics of the existing HydroFrame coils (K090357, K100454 and K103758) with the additional models presented in this 510(k) submission. The devices,

- Have the same intended use
- Use the same operating principle
- Incorporate the same basic coil design
- Use similar construction and material
- Are packaged and sterilized using same material and processes

The line extension of the HydroFrame 10 coils (includes addition of sizes from 1mm to 9 mm secondary wind diameter with lengths from 2 cm to 36 cm) and change in the Stretch Resistance Member Material from Polyethylene Terephthalate (PET) to PET or Polyolefin Elastomer (Engage™) does not change the indications for use of the coils and is not a change to the fundamental scientific technology. The performance data below shows the device will perform as well as the previously marketed device.

**Table I: Predicate Device vs Subject Device Comparison Table**

	<b>Existing HydroFrame 10 (Predicate Device, (K090357, K100454 and K103758)</b>	<b>HydroFrame 10 Line Extension (Subject Device</b>
<b>Intended Use</b>		

Intended Use Statement	The HydroCoil Embolic System (HES) are intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.	Same
<b>Performance</b>		
Function	The coils are used for the endovascular embolization of aneurysms, other neurovascular abnormalities such as arteriovenous malformations, arteriovenous fistulae and arterial and venous embolizations in the peripheral neurovasculature.	Same
Anatomical Location	General intravascular use, including the neuro and peripheral vasculature.	Same
<b>Implantable Embolization Coil</b>		
Coil Shape	3D - Spherical	Same
Primary Coil Wire OD	0.00150 inch, .00175 inch, .00200 inch, .00225 inch	Same
Coil Implant Diameter	2 – 12 mm	1 – 9 mm
Coil Restrained Length	2 – 43 cm	2 - 36 cm
Coil Gap	Closed	Same
Delivery pusher length	195 cm	Same
<b>Material</b>		
Main Coil Wire	Platinum/Tungsten Alloy (Pt/W: 92/8)	Same
Coil-to-Pusher Coupler	Platinum/Iridium (Pt/Ir: 90/10)	Same
Adhesive	Ultraviolet Curing Adhesive	Same
Implant to Pusher Filament	Polyolefin Elastomer	Same
Stretch resistant (SR)	Polyethylene Terephthalate (K103758) or Polyolefin Elastomer (K090357, K100454)	Same
Hydrogel	Hydrophilic Acrylic Copolymer	Same
<b>Other Attributes</b>		
Detachment System	Detachment Controller; stand alone, hand held battery operated unit detaches the coil implant	Same
Catheter compatibility	Compatible with 10-system microcatheters (minimum ID of 0.0165")	Same

MRI compatibility	Yes	Same
Method of Supply	Sterile and single use (Gamma Radiation)	Same
Package Configuration	Placed in Introducer Sheath, Dispenser Coil, Pouch, and Shipping Carton	Same

PERFORMANCE DATA [807.92(b)]

Results of the verification and validation testing (**Table II**) indicate that the product meets established performance requirements, and is substantially equivalent for its intended use.

**Table II: Design Verification and Validation Test Summary**

Bench Testing	Result
<b>Visual Inspection:</b> Using a microscope, inspect HydroFrame Coils per device drawing, PDH-HFRM-ATP.	All test samples passed testing.
<b>Dimensional Measurement:</b> Using a microscope, inspect HydroFrame Coil's secondary wire diameter.	All test samples passed testing.
<b>Simulated Use:</b> The test simulate the use of HydroFrame coils <i>in-vitro</i> using a cerebrovascular benchtop model.	All test samples passed testing.
<b>Reposition Time:</b> The test reposition the device within simulated use bench top model and determine the performance of the gel.	All test samples passed testing.
<b>Advancement/Retraction Force:</b> The test measures the maximum force required to advance and retract the coil through the microcatheter after 30 minutes.	All test samples passed testing.
<b>Expanded Gel Diameter:</b> The HydroFrame coils are detached from the pusher and the expanded diameter of the hydrogel (post hydration) are measured using a microscope.	All test samples passed testing.
<b>Spring Constant:</b> The spring constant force (determination of maximum force to break monofilament) of the coil is measured.	All test samples passed testing.
<b>Weld Tensile:</b> The coil/coupler weld tensile strength is tested and measured.	All test samples passed testing.

**Biocompatibility Summary – HydroFrame 10 Implant**

Biocompatibility	Test Standard	Results
<b>Cytotoxicity</b>		
MEM Elution Test	ISO 10993-5	Non-toxic
ISO Cell Culture Agar Overlay	ISO 10993-5	Non-toxic
<b>Sensitization</b>		

Sensitization-Guinea Pig Maximization Test	ISO 10993-10	No sensitizer response
<b>Irritation</b>		
ISO Intracutaneous Reactivity Evaluation Test	ISO 10993-10	Non-irritant
<b>Hemocompatibility</b>		
Hemolysis	ISO 10993-4	Non-hemolytic
Prothrombin Time Assay - ISO	ISO 10993-4	No adverse effect on coagulation time
<b>Systemic Toxicity</b>		
Systemic toxicity (IV injection)	ISO 10993-11	Non-toxic
Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Non-pyrogenic
<b>Genetic Toxicology</b>		
Bacteria Reverse Mutation Assay (Ames Test)	ISO 10993-3	Negative response for mutagenicity
<b>Intramuscular Implantation</b>		
7-day Muscle Implantation	ISO 10993-6	Non-irritant
13-week Intramuscular Implantation Test	ISO 10993-6	Non-irritant
26-week Intramuscular Implantation Test	ISO 10993-6	Non-irritant

#### Biocompatibility Summary – V-Trak™ or V-Trak™ Advanced Delivery Pusher

Biocompatibility	Test Standard	Results
<b>Cytotoxicity</b>		
MEM Elution Test	ISO 10993-5	Non-toxic
ISO Cell Culture Agar Overlay	ISO 10993-5	Non-toxic
<b>Sensitization</b>		
Sensitization-Guinea Pig Maximization Test	ISO 10993-10	No sensitizer response
<b>Irritation</b>		
ISO Intracutaneous Reactivity Evaluation Test	ISO 10993-10	Non-irritant
<b>Hemocompatibility</b>		
Hemolysis	ISO 10993-4	Non-hemolytic
Prothrombin Time Assay - ISO	ISO 10993-4	No adverse effect on coagulation time
<b>Systemic Toxicity</b>		
Systemic toxicity (IV injection)	ISO 10993-11	Non-toxic

Rabbit Pyrogen Test (material mediated)	ISO 10993-11	Non-pyrogenic
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## CONCLUSIONS

Based on the 510(k) summary and information provided herein, we conclude the subject device, HydroFrame 10 in the HES, is substantially equivalent in its intended use, design, material, performance, and the underlying fundamental scientific technology used, to the predicate HydroFrame 10, K090357, K100454 and K103758.