

JUL 03 2014

K44134

- **510(k) Summary**

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the POD™ System.

**Sponsor/Applicant Name and Address**

Penumbra, Inc.  
1351 Harbor Bay Parkway  
Alameda, CA 94502, USA

**Sponsor Contact Information**

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**Date of Preparation of 510(k) Summary**

April 30, 2014

**Device Trade or Proprietary Name**

POD™ System

**Device Classification**

Regulatory Class: II  
Classification Panel: Neurology  
Classification Name: Neurovascular/vascular embolization device  
Regulation Number: 21 CFR 882.5950, 21 CFR 870.3300  
Product Code: HCG, KRD

**Predicate Devices**

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K103305 / 26-Jan-2011	Penumbra Coil System	Penumbra, Inc.
K120330 / 02-Apr-2012	Penumbra Coil System	Penumbra, Inc.

## Predicate Comparison

	Penumbra Coil System	POD System
510(k) No.	K103305 & K120330	To be determined
Classification	Class II, HCG, KRD	Same
Indication	Indicated for the endovascular embolization of: <ul style="list-style-type: none"> <li>• Intracranial aneurysms</li> <li>• Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae</li> <li>• Arterial and venous embolizations in the peripheral vasculature</li> </ul>	Same
<b>Materials</b>		
Coil	Platinum/Tungsten, Nitinol	Same
Detachment Pusher	Stainless steel, Polymer, Platinum/Iridium, Nitinol	
Detachment Handle Shell/Funnel	Plastic	
<b>Dimensions/Shape</b>		
Coil Secondary Length	1-60 cm	Same
Coil Secondary Diameter	2-32 mm	4-8 mm*
Coil Secondary Shape	Complex (Standard, Soft, Extra Soft), Helical (Curve), J	Complex
<b>Accessories</b>		
Introducer Sheath	Polypropylene (color: orange)	Same
<b>Packaging Materials</b>		
Coil Hoop	Polyethylene	Same
Pouch	Polyester/Polyethylene/Tyvek	Same
Display Carton	SBS Paperboard	Same
<b>Sterilization/Shelf Life</b>		
Sterilization Method	EtO	Same
Shelf Life	8 years	Same
Detachment Handle Shelf Life	3 years	Same

\*The proximal segment of the coil will have a reduced secondary diameter

## Device Description

The POD System functions to selectively embolize targeted segments of the vasculature by packing a sufficient quantity of soft platinum coils to achieve occlusion in an equivalent fashion to existing bare-platinum embolization coils. The POD System

consists of three components: a Coil Implant attached to a Detachment Pusher and a Detachment Handle.

### **Intended Use**

The POD System is indicated for the embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

### **Summary of Non-Clinical Data**

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding safety and effectiveness of the device follows.

Included in this section are descriptions of the testing's, which substantiates the safe and effective performance of the POD System as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- MRI Compatibility
- Design Validation (GLP Animal Testing)

The subject POD System met all established requirements.

### **Biocompatibility Testing**

Non-clinical testing found POD to be biocompatible according to the requirements of EN ISO 10993 requirements. Biocompatibility for POD was derived from studies on the predicate device. Studies were selected in accordance with EN ISO 10993 -1 guidelines (Biological Evaluation of Medical Devices). All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The following tests were performed:

Test	Pass/Fail
<i>In Vitro</i> Cytotoxicity (MEM Elution)	Pass
Sensitization (Kligman Maximization)	Pass
Irritation (Intracutaneous Reactivity)	Pass
<b>Systemic Toxicity</b>	
Acute Toxicity (ISO Systemic Injection)	Pass
<i>In Vivo</i> Sub-acute / Sub-chronic Toxicity	Pass
Sub-chronic Toxicity Subchronic (30-Day) Intravenous Toxicity Study - Mice	Pass
Materials Mediated Pyrogen - Rabbit	Pass
<b>Genotoxicity</b>	
Mouse Lymphoma	Pass
Ames Mutagenicity	Pass
<i>In Vivo</i> Mouse Micronucleus	Pass
Implantation GLP Study – Penumbra Coil System in Swine Venous Pouch Aneurysm Model	Pass
Intramuscular Implant Test 13 Week Duration	Pass
<b>Hemocompatibility</b>	
Hemolysis	Pass
Complement Activation	Pass
Dog Thrombogenicity	Pass

### Bench-top Testing

The physical, mechanical and performance testing of the POD System components demonstrate that the devices are substantially equivalent to the currently marketed predicate devices.

Design Verification testing was conducted to evaluate the physical and mechanical properties of POD System components. All studies were conducted using good scientific practices and statistical sampling methods as required by the Penumbra Design Control procedures. All testing was performed using units which were 2x sterilized and met finished goods release requirements. The tests performed on the POD System components included:

Attribute	Specification	Results
<b>Dimensional / Visual Inspection</b>	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.	100% Pass
<b>Fatigue Testing</b>	The Coil Implant shall retain its secondary shape after being cycled into/out of introducer sheath 5 times	100% Pass
<b>Friction Testing</b>	Push/pull friction acceptable through an 0.025in ID microcatheter	100% Pass
<b>Stiffness Testing</b>	Appropriate stiffness per coil specifications	100% Pass
<b>Simulated Use Flow Model Testing</b>	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of	100% Pass

Attribute	Specification	Results
	finished goods (clinically acceptable) product.	
<b>Coil Dimensional Inspection (after simulated use testing)</b>	These evaluations confirm that the units used in this Design Verification testing withstood the simulated use testing	100% Pass
<b>Distal System Tensile Test</b>	Coil Implant and Detachment Pusher joints has sufficient tensile strength	100% Pass

All testing met specification. The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the POD System are acceptable for the intended use and substantially equivalent to the predicate devices.

### **MRI Compatibility**

Penumbra consulted with an MR scanning expert and concluded minor design changes will have no impact on RF heating, and the same MRI conditions that are safe for the Penumbra Coil System Coil Implants arrays will also be safe for the POD Coil Implants.

### **Design Validation (GLP Animal Testing)**

The existing Penumbra Coil System GLP animal study fully characterizes the POD System's interaction with the vasculature. No additional animal testing is required for the POD System.

### **Summary of Substantial Equivalence**

The POD System is substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 3, 2014

Penumbra, Inc.  
Mr. Charles Denault  
Regulatory Affairs Specialist  
1351 Harbor Bay Parkway  
Alameda, California 94502

Re: K141134  
Trade/Device Name: POD system  
Regulation Number: 21 CFR 882.5950  
Regulation Name: Neurovascular Embolization Device  
Regulatory Class: Class II  
Product Code: HCG and KRD  
Dated: June 4, 2014  
Received: June 6, 2014

Dear Mr. Denault:

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

Page 2 - Mr. Charles Denault

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,

**Felipe Aguel -S**

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)  
K141134

Device Name  
POD (Penumbra Occlusion Device) System

Indications for Use (Describe)

The POD System is indicated for the embolization of:

Intracranial aneurysms

Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Felipe Aguel -S** Date: 2014.07.03 12:31:39  
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