# 510(k) Summary

per 21 CFR §807.92

| Submitter's Name and Address | AGA Medical Corporation  
5050 Nathan Lane North  
Plymouth, MN 55442 |
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<tr>
<td>Establishment Registration No:</td>
<td>2135147</td>
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</table>
| Contact Name and Information | Sherry Kollmann  
Senior Regulatory Affairs Specialist  
Phone: 651-756-5463  
Fax: 763-647-5932  
e-mail: skollmann@sjm.com |
| Trade Name | AMPLATZER® Vascular Plug 4 |
| Common Name | Vascular Embolization Device |
| Classification Name: | Device Embolization, Vascular |
| Classification | Class II, 21 CFR 870.3300 |
| Product Code | KRD |
| Predicate Devices | AMPLATZER® Vascular Plug II  
510(k) K071125, Reg. No.  
870.3300; Product Code: KRD |
| | AMPLATZER® Vascular Plug II Extended Sizes  
510(k) K071699, Reg. No.  
870.3300; Product Code: KRD |
| Device Description | The AMPLATZER Vascular Plug 4 (AVP4) is a self expanding, Nitinol mesh occlusion device. The device has a radiopaque marker band at each end and a micro screw attachment at one end for attaching to the delivery wire. The device is an extension of the previously approved AMPLATZER Vascular Plugs and has the identical indications for use: arterial and venous embolizations in the peripheral vasculature. Included in the AVP4 device package are:  
- Loader - consisting of two tubes, one inside the other with a stainless steel spring attached to extend the inner retractable tube  
- Delivery Wire - comprised of a PTFE covered coil with core wire and attached end screw |
| Intended Use of Device | The AMPLATZER® Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature. |
Traditional 510(k) Submission
Amplatzer® Vascular Plug 4

The AMPLATZER® Vascular Plug 4 incorporates substantially equivalent device materials, packaging materials, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the AGA predicate devices, AMPLATZER® Vascular Plug II (K071125, approved September 9, 2003) and AMPLATZER® Vascular Plug II Extended Sizes (K071699, approved August 15, 2007).

In comparison to the predicate device, the AVP4 incorporates the following modifications:

- A change to the shape of the device
- Adaptation of the loader and delivery wire allowing the AVP4 to be delivered through 4 Fr and 5 Fr 0.038" guidewire-compatible diagnostic catheters versus standard off-the-shelf guide catheters
- A change to the finish of the device Nitinol base wire, from black oxide (BO) to chemically etched (CE) finish

The modifications noted above have not altered the intended use or the fundamental scientific technology of the predicate device.

The AMPLATZER® Vascular Plug 4 was subjected to bench testing, biocompatibility testing, and materials testing to support a determination of substantial equivalence to the predicate devices cited. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

To demonstrate substantial equivalence of the AMPLATZER Vascular Plug 4 to the predicate devices, both in-vitro and in-vivo testing was performed and outlined below:

The following in-vitro performance testing and/or assessment was completed on the AMPLATZER® Vascular Plug 4:

<table>
<thead>
<tr>
<th>Sterilization</th>
<th>Fatigue</th>
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<tr>
<td>Material Characterization</td>
<td>Product Performance Qualification</td>
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<tr>
<td>Simulated Device Use (Design Verification)</td>
<td>Packaging Performance</td>
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<tr>
<td>Corrosion Resistance</td>
<td>Biocompatibility (Implant and delivery system, ISO 10993-1)</td>
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<tr>
<td>Chemical Characterization (ISO 10993-18)</td>
<td>Toxicology Risk Assessment (ISO 10993-17)</td>
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<td>MRI</td>
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The following in-vivo performance tests were completed on the AMPLATZER® Vascular Plug 4:

<table>
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<tr>
<th>Occlusion Canine Study</th>
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<tr>
<td>Serum Analysis (Porcine Study)</td>
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<tr>
<td>Acute Canine Study</td>
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Traditional 510(k) Submission
Amplatzer® Vascular Plug 4

Conclusion

Based on the intended use, technological characteristics, and safety and performance testing, the AMPLATZER® Vascular Plug 4 has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the AGA currently marketed predicate devices.
AGA Medical Corporation  
c/o Sherry Kollmann, RAC  
Senior Regulatory Affairs Specialist  
5050 Nathan Lane North  
Plymouth, MN 55442

Re: K113658  
Trade/Device Name: Amplatzer Vascular Plug 4  
Regulation Number: 21 CFR 870.3300  
Regulation Name: Device Embolization, Vascular  
Regulatory Class: Class II  
Product Code: KRD  
Dated: May 16, 2012  
Received: May 17, 2012

Dear Ms. Kollmann:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRHClinicalRegulations/ucm15809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

[Signature]

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K113658

Device Name: AMPLATZER® Vascular Plug 4

Indications for Use: The AMPLATZER® Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature.

Prescription Use 

And/or

Over-The-Counter Use

(Please do not write below this line-continue on another page of needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113658