K071699

510(k) SUMMARY of Safety and Effectiveness

I. Applicant Information:

Date Prepared:	June 19, 2007
Submitter:	AGA Medical Corporation
Address:	5050 Nathan Lane North Plymouth, MN 55442
Establishment Registration No.	2135147
Contact Person:	Jodi L. Raus, RAC Director of Regulatory Affairs
Telephone Number:	(763) 531-3056
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AUG 15 2007

II. Device Information:

Trade Name:	AMPLATZER® Vascular Plug II
Common Name:	Catheter Delivery System
Classification Name:	Device, Embolization, Vascular
Classification:	Class II, 21 CFR 870.3300
Product Code:	KRD
Predicate Device:	AMPLATZER® Vascular Plug II 510(k) No. K071125, Reg. No. 870.3300; Product Code: KRD

Predicate Device Intended Use: *The AMPLATZER® Vascular Plug II is indicated for arterial and venous embolizations in the peripheral vasculature.*

Device Description: The AMPLATZER® Vascular Plug II is a sterile, single-use, triple-lobed, self-expanding Nitinol mesh occlusion device, with a screw-attachment for a Delivery Wire and radiopaque marker bands at both ends. The Plug is attached to a 135 cm Delivery Wire with a stainless steel screw. The AMPLATZER® Vascular Plug II is provided contained within a Loader Device that facilitates loading into a delivery catheter. The Delivery Wire comes coiled in a hoop dispenser

The AMPLATZER® Vascular Plug II is available in fully-expanded diameters of: 3 mm to 22 mm.

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

Comparison to Predicate Device: The AMPLATZER® Vascular Plug II is substantially equivalent to the predicate device cleared by K071125. The two devices are both embolization devices with identical intended uses. Both devices have exactly the same patient-contacting materials, and have the same Nitinol Delivery Wire. Both devices have the same triple-lobed, multiple wire layer design. Both devices come preloaded in a loader device. The two devices have the same operating principle, where a self-expanding Nitinol mesh device is retrieved in a loader, delivered to the desired embolization site through a delivery catheter and, upon release, both devices expand to occlude the vessel or desired embolization site.

One minor modification was made to the AMPLATZER® Vascular Plug II:

- Extended size range, with the addition of 3 mm, 18 mm, 20 mm and 22 mm devices to the currently-approved size range of 4-16 mm devices.

Test Data: Verification and validation testing confirms that the functional characteristics of the AMPLATZER® Vascular Plug II are substantially equivalent to the predicate device cited. This included radial force testing, handoff and advancement forces, device deployment, recapture and detachment verification and overall strength determinations. Animal testing was also performed to validate the product under simulated conditions of use.

Summary: Based on the technical information, intended use, laboratory verification tests and *in vitro* and *in vivo* performance information provided, the AMPLATZER® Vascular Plug II is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

AGA Medical Corporation
c/o Ms. Jodi L. Raus
5050 Nathan Lane North
Plymouth, MN 55442

Re: K071699
Trade/Device Name: AMPLATZER Vascular Plug II
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: July 19, 2007
Received: July 20, 2007

Dear Ms. Raus:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

Ms. Jodi L. Raus

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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K071699

Device Name: **AMPLATZER® Vascular Plug II**

Indications for Use:

The AMPLATZER® Vascular Plug II is indicated for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X AND/OR Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071699