DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

January 10, 2017

AGA Medical Corporation
Gabrielle Zaeska
Senior Regulatory Affairs Specialist
5050 Nathan Lane North
Plymouth, MN 55442

Re: H070005
HUD NUMBER: 07-0178
AMPLATZER™ Post-Infarct Muscular VSD Occluder
Filed: June 18, 2007
Amended: July 13, 2007, August 20, 2007, September 19, 2007, November 5, 2007, January 22, 2008, January 25, 2008, February 7, 2008, March 20, 2008, May 13, 2008, July 3, 2008, December 9, 2008, April 10, 2009, June 16, 2009, October 1, 2009, March 15, 2010, September 7, 2010, January 6, 2011, March 4, 2011, March 16, 2011, July 7, 2011, February 21, 2012, September 24, 2012, March 1, 2013, July 5, 2016, August 8, 2016, September 29, 2016
Procode: MLV

Dear Ms. Zaeska:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the AMPLATZER Post-Infarct Muscular VSD Occluder. The AMPLATZER Post-Infarct Muscular VSD Occluder is a percutaneous transcatheter occlusion device intended for closure of post myocardial infarct muscular ventricular septal defects in patients who are not satisfactory surgical candidates. We are pleased to inform you that your HDE is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 5 years.

Continued approval of this HDE is contingent upon the submission of periodic reports, required

under 21 CFR 814.126, at intervals of one year (unless otherwise specified) from the date of approval of the original HDE. Two (2) copies of this report, identified as "Annual Report" and bearing the applicable HDE reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.126.

In addition to the above, and in order to provide continued reasonable assurance of safety and probable benefit of the device, an HDE holder is required to maintain records of the names and addresses of the facilities to which the humanitarian use device (HUD) has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA and include this information in your Annual Report, separately for each model (if applicable).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Two (2) copies of the report, identified as an "OSB Lead HDE Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable HDE reference number, should be submitted to the address below.

1. OSB Lead Post-Approval Study – *AMPLATZER Post Infarct Muscular Ventricular Septal Defect (PIVSD) Occluder:* The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. On December 7, 2016, you agreed to conduct a study as follows:

   The study will evaluate the long-term safety and effectiveness of the AMPLATZER PIVSD Occluder for use in transcatheter closure of muscular ventricular septal defects following a myocardial infarction. The study will be a retrospective, non-randomized, observational study. Data will be collected from previously attempted emergency/compassionate use cases. A random sample of the implant attempts from 2011 to present will be used to identify the potential subjects. Data collection will happen sequentially until data on a minimum of 30 subjects from up to 50 U.S. centers with hemodynamically significant muscular VSDs (demonstrated by echocardiography or angiography) following a myocardial infarction who were implanted with an AMPLATZER PIVSD Occluder are obtained. In the event that data from 30 subjects cannot be obtained retrospectively (due to patient death or inability to obtain consent), data will be collected prospectively until data on a minimum of 30 subjects is obtained. The purpose of the study will be to assess the following endpoints:

- Technical success defined as the ability to successfully place the device in the defect;
- Acute closure defined as the absence of a residual shunt ≥3mm at the post-procedure visit;
- Chronic closure defined as the absence of a residual shunt ≥3mm at 6 months post-procedure;
- Acute survival defined as survival at 24 hours post-procedure; and
- Chronic survival defined as survival at 6 months post-procedure.

All echocardiograms will be reviewed and assessed by an Echocardiography Core Laboratory for quantification of shunts. Subjects will have data collected from visits that occurred at baseline, implant, post-procedure, and 6 months post-procedure.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the HDE.

In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a HDE Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Within 30 days of your receipt of this letter, you must submit a HDE supplement that includes a complete protocol of your post-approval study described above. Your HDE supplement should be clearly labeled as “OSB Lead HDE Post-Approval Study Protocol" as noted above and submitted in triplicate to the address below. Please reference the HDE number above to facilitate processing. If there are multiple protocols being finalized after HDE approval, please submit each protocol as a separate HDE supplement.

Before making any change affecting the safety or effectiveness of the device, you must submit an HDE supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.108 and 814.39 except a request for a new indication for use of a HUD. A request for a new indication for use for an HUD shall comply with the requirements set forth in 21 CFR 814.110 which includes obtaining a new designation of HUD status for the new indication for use and submission of an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to

report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

This device may not be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. See section 520(m)(3) of the Federal Food, Drug, and Cosmetic Act.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your HDE by making available, among other information, a summary of the safety and probable benefit of the device upon which the approval was based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch (HFA-305), Room 1061, 5630 Fishers Lane, Rockville, MD 20852. The written request should include the HDE number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of an HDE. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this HDE submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the

labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing.

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If you have any questions concerning this approval order, please contact Jennifer Bastijanic at (240) 402-3049 or jennifer.bastijanic@fda.hhs.gov.

Sincerely yours,

for

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