DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 9, 2016

AGA Medical Corporation
(wholly owned by St. Jude Medical Corporation)
Mary Johnson
Specialist I, Regulatory Affairs
5050 Nathan Lane
Plymouth, Minnesota 55442

Re: K162228
Trade/Device Name: AMPLATZER TorqVue Low Profile Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 5, 2016
Received: August 8, 2016

Dear Mary Johnson:

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,

Brian D. Pullin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162228

Device Name
AMPLATZER TorqVue Low Profile Delivery Catheter

Indications for Use *(Describe)*
The AMPLATZER™ TorqVue™ LP Catheter is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or 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.

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510(K) SUMMARY

Submitter:	AGA Medical Corporation A wholly owned subsidiary of St. Jude Medical 5050 Nathan Lane Plymouth, MN
Contact Person:	Mary Johnson, Regulatory Affairs Specialist I Phone: 651-756-2213 Fax: 651-756-5744 E-mail: mjohnson16@sjm.com
Date Prepared:	August 5, 2016
Trade Name:	AMPLATZER® TorqVue® Low Profile Delivery Catheter
Common Name:	Catheter Delivery System
Classification:	Class II, 21 CFR 870.1250 Catheter, Percutaneous
510(k) Number:	K162228
Product Code:	DQY
Predicate Device(s):	AMPLATZER TorqVue Low Profile Delivery System (K131063)

Device Description:

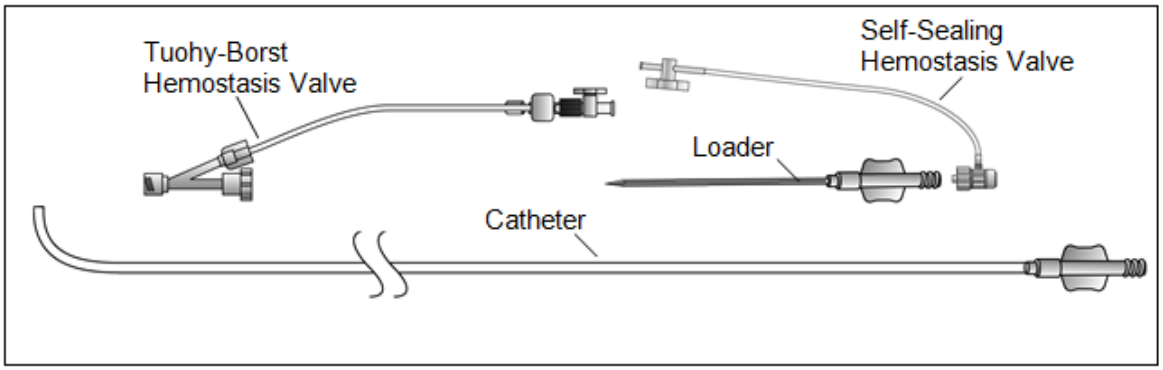
The AMPLATZER TorqVue Low Profile Delivery Catheter (TVLPC) is an extension of the AMPLATZER TorqVue Low Profile Delivery System (TVLP) product line. The TVLPC is identical to the TVLP with the exception of a delivery wire, which is omitted on the TVLPC catheter only product.

The TorqVue LP Catheter includes a catheter, loader, Tuohy-Borst hemostasis valve, and a self-sealing hemostasis valve. The TorqVue LP Catheter is intended for use with AMPLATZER devices packaged with a delivery wire.

Figure 1 illustrates the delivery system and identifies the following essential components:

- Catheter – Single-lumen catheter that is used to deliver the device after it has been positioned by the physician. The body of the catheter is radiopaque to increase visibility when using fluoroscopy. The distal end of the catheter is curved approximately 90°.
- Tuohy-Borst hemostasis valve – An adapter designed to control back-bleeding from the Delivery Catheter.
- Loader – catheter short tube with luer fittings that aids in placing the desired devices into the Delivery Catheter.
- Self-sealing hemostasis valve – An adapter designed to control back-bleeding from the Delivery Catheter. The self-sealing valve provides additional sealing capabilities for use with delivery wires of smaller diameters.

Figure 1. TVLPC Components



Intended Use:

The AMPLATZER TorqVue LP Catheter is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Comparison to predicate:

The AMPLATZER TorqVue LP Catheter is an extension of the AMPLATZER TorqVue Low Profile Delivery System (K131063) product line. The predicate TorqVue LP Delivery System includes a catheter, loader, Tuohy-Borst hemostasis valve, delivery wire, and plastic vise for the delivery of AMPLATZER occlusion devices, while the TorqVue LP Catheter includes a catheter, loader, Tuohy-Borst hemostasis valve, and a self-sealing hemostasis valve. The self-sealing hemostasis valve (referred to as hemostasis valve in AVP4 documentation) is identical to the one included with the currently marketed AMPLATZER Vascular Plug 4 (K113658).

The TVLPC differs from the TVLP in the following ways:

- TVLPC Device only offered in 4 Fr size
- Removal of Delivery Wire
- Addition of Self-Sealing Hemostasis Valve

Table 1 summarizes the included components for each device.

Table 1. TVLPC vs. TVLP and AVP 4 Component Summary

	TVLPC	TVLP	AVP4
Catheter	✓	✓	
Loader	✓	✓	
Tuohy-Borst hemostasis valve	✓	✓	
Delivery Wire		✓	
Vise		✓	
Self-sealing hemostasis valve	✓	4 Fr	✓
Sizes offered	4Fr	5 Fr	n/a

Functional and Safety Testing:

The components of the TVLPC are identical to the 510(k) cleared predicate TVLP and AVP4 devices. Design Verification and Design Validation testing has been performed and has been provided in cleared applications for the predicate TVLP (K131063) and AVP4 (K113658) devices. Separate packaging validation has been completed on the subject device.

Conclusion:

AGA Medical Corporation considers the 4 Fr AMPLATZER TorqVue Low Profile Delivery Catheter to be substantially equivalent to the TorqVue Low Profile Delivery System. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use as identical components merely packaged differently from predicate devices.