4 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

4.1 Applicant Information

Date Prepared: March XX, 2013

Submitter: AGA Medical Corporation

Address: 5050 Nathan Lane North
Plymouth, MN 55442

AUG 15 2013

Establishment
Registration No: 2135147

Contact Person: Heather M Taylor
Sr. Regulatory Affairs Specialist

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4.2 Device Information

Trade Name: AMPLATZER® TorqVue® Low Profile Delivery System

Common Name: Delivery System

Classification Name: Catheter, Percutaneous

Classification: Class II, 21 CFR 870.1250

Product Code: DQY

Predicate Devices: AMPLATZER® TorqVue® Delivery System

510(k) K072313, Reg. No. 870.1250; Product Code: DQY

Predicate Device Intended Use: The AMPLATZER® TorqVue® Delivery System 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.

AMPLATZER® TorqVue® Low Profile Delivery System

510(k) K080757, Reg. No. 870.1250; Product Code: DQY

Predicate Device Intended Use: The AMPLATZER TorqVue LP delivery system is intended to provide a pathway through which devices are introduced into the peripheral vasculature.

Device Description: The AMPLATZER TorqVue Low Profile Delivery System is a sterile, single-use device designed to facilitate the introduction of devices to chambers and coronary vasculature of the heart and for introducing therapeutic devices to a location within the peripheral vasculature.

The catheter has a single lumen for passage of devices with maximum outer diameters of 4 and 5 French. The catheters will be provided in 60 cm and 80 cm usable lengths. The system includes the following components:

- Delivery Catheter – used to deliver devices
- Loader– used to help introduce the selected implantable device into the delivery catheter
- Delivery Wire (optional) – attaches to the implantable device and facilitates advancement through the catheter, placement and, if desired, recapture of the specified implantable device. [If this surgical accessory (Product Code = DWS) is included, the labeling will specify compatibility with the appropriate implantable devices.]
- Plastic Vise (included with delivery wire) – a handle that is attached to the Delivery Wire by means of a set screw
- Hemostasis Valve– used on the proximal end of the Loader to minimize bleeding from the Delivery Catheter and for flushing air from the system

Intended Use: The AMPLATZER® TorqVue® Low Profile Delivery System 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 Devices:	The AMPLATZER® TorqVue® Low Profile Delivery System is substantially equivalent to the predicate devices cleared by K072313 and K080757. This submission seeks to add a cardiac indication to the already cleared K080757. All systems are handheld catheter systems designed to facilitate access and placement of specified implantable devices within the chambers and coronary vasculature of the heart. All three delivery catheters are single lumen design with a hemostasis valve. The device included in this submission is identical in design to the already cleared K080757, and is using the already cleared K072313 to support the cardiac indication for use.
Test Data:	Verification and validation testing confirms that the functional characteristics of the AMPLATZER® TorqVue® Low Profile Delivery Systems are substantially equivalent to the predicate devices cited. This included catheter integrity, catheter kink resistance, leak resistance, hub strength and the ability to deliver various implantable devices.
Summary:	Based on the technical information, intended use, laboratory verification tests and in vitro performance information provided, the AMPLATZER® TorqVue® Low Profile Delivery System is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 15, 2013

St. Jude Medical
C/O Heather Taylor
5050 Nathan Lane North
Plymouth, MN 55442 US

Re: K131063
Trade/Device Name: AMPLATZER TorqVue Low Profile Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: July 25, 2013
Received: July 26, 2013

Dear Ms. Taylor:

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 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. 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,

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

Enclosure

3 STATEMENT OF INDICATIONS FOR USE

510(k) Number: K131063

Device Name: AMPLATZER® TorqVue® Low Profile Delivery System

Indications for use:

The AMPLATZER® TorqVue® Low Profile Delivery System is indicated to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Prescription Use x **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number: K131063