DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 23, 2016

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

Re: K163000
Trade/Device Name: The AMPLATZER TorqVue 45° x 45° Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 29, 2016
Received: December 1, 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)*
K163000

Device Name
AMPLATZER™ TorqVue™ 45° x45° Delivery Sheath

Indications for Use *(Describe)*
The AMPLATZER™ TorqVue™ 45° x 45° Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.

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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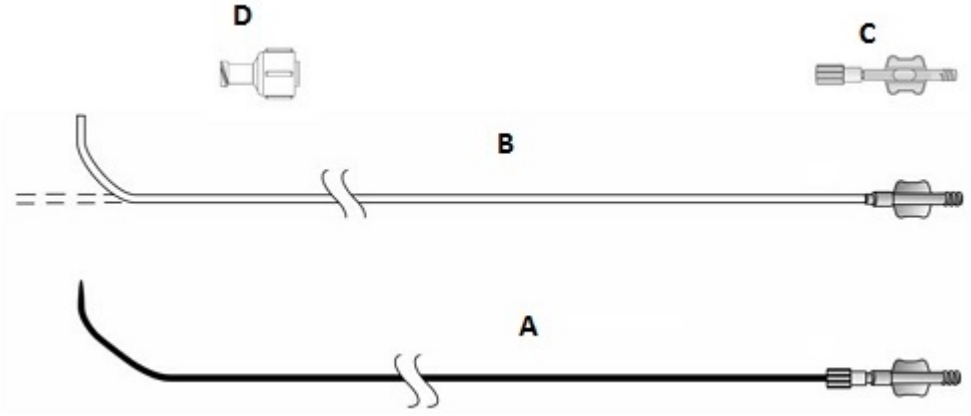
510(K) SUMMARY

510(k) Number	K163000
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:	October 27, 2016
Trade Name:	AMPLATZER™TorqVue™ 45°x45° Delivery Sheath
Common Name:	Catheter Delivery System
Classification:	Class II, 21 CFR 870.1250 Catheter, Percutaneous
Product Code:	DQY
Predicate Device(s):	**Primary Predicate**-AMPLATZER™ TorqVue™ LA and AMPLATZER TorqVue 45°x45° (14 Fr) Delivery Sheaths (K120120) **Secondary Predicate**-AMPLATZER™ TorqVue™ 45°x45° Delivery Sheath 9-13 Fr sizes (K083214)

Device Description:	The AMPLATZER™ TorqVue™ 45°x45° 80 cm Delivery Sheath (TV45x45 80cm) is an extension of the AMPLATZER™ TorqVue 45x45 Delivery Sheath (TV45x45 100cm) product family (K120120 and K083214) and is available in both a 12Fr and 14Fr sheath size. The TV45x45 80cm is identical to the cleared TV45x45 (100cm) family of sheaths with the exception of having a shorter 80 cm length and the tip taper length of the 12Fr (80cm) dilator modeled on the taper length of the existing 14 Fr TV45x45 (100cm) dilator. The 80 cm length is consistent with several TorqVue Delivery System products including the TorqVue™ Delivery system (ITV) cleared under submission K072313 and the TorqVue™ (TVLA) delivery sheaths cleared under submission K120120. Similar to the predicate the TorqVue 45°x45° 80 cm Delivery Sheath includes a flush adapter, sheath and dilator. **Figure 1** illustrates the delivery sheath and identifies the following essential components: • **Sheath (A)**-Catheter that enables device delivery by the physician. The body of the sheath is radiopaque for visibility under fluoroscopy. For added visibility the sheath also has a radiopaque marker band near the distal tip. • **Dilator (B)**-Used to ease penetration of tissue and minimize vessel trauma during sheath insertion into and through the vasculature. For added visibility the dilator is radiopaque for visibility under fluoroscopy. • **Flush Adaptor**-The flush adaptor for both the 12F**(C)** and 14F **(D)** sheaths enables connection with syringes for flushing the sheath lumen. **Figure 1. AMPLATZER TV 45x45 (80cm) Components** 
Indications for Use:	The AMPLATZER™ TorqVue™ 45°x45° Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.

Comparison to predicate:

AMPLATZER™ TorqVue 45°x45° (80cm) Delivery Sheath is an extension of the AMPLATZER™ TorqVue 45°x45° product family (K083214, K120120) line.

The AMPLATZER™ TorqVue 45°x45° 80cm subject device is available in either 12 or 14Fr and shares the same design (with the exception of being 80cm length versus 100cm), materials, accessories, and manufacturing processes as the predicate. The dilator used with the 12 Fr subject device will be updated to have the same tip geometry as the predicate TV45x45 100cm 14 Fr device (the same dilator tip taper length and 80cm length is also consistent with the marketed AMPLATZER TorqVue LA (TVLA1 and TVLA 2) devices, K120120).

Table 1 summarizes the changes being made to 12 and 14 Fr versions of the TV45x45 device.

Table 1. TV45x45 Change Summary

	TV45x45 80 cm (Subject)	**TV45x45 14Fr 100cm (Predicate-K120120)**	**TVLA 1&2 (Predicate-K120120)**
Device Usable Length	80 cm	100 cm	80 cm
Tip Taper Length	Extended tip taper length	Extended tip taper length	Extended tip taper length

[1]The 14Fr size was cleared under K120120; the remaining Fr sizes in the TV45x45 family were cleared earlier under K083214.

Functional and Safety Testing:

The intended use, components, materials and fundamental design of the TV45x45 80 cm are identical to the cleared predicate TV45x45 (100cm) device (TV45x45 device family cleared in two submissions K083214 and K120120). Design Verification and Design Validation testing have been previously performed and provided in cleared applications for the predicate device (TV 45x45 (100 cm, K120120 and K083214), TVLA1 and TVLA 2 Delivery Sheath (K120120) devices). Separate packaging design verification has been completed on the subject device.

Conclusion:

AGA/SJM considers the TorqVue 45°x45° 80 cm Delivery Sheath to be substantially equivalent to the TorqVue 45°x45° 100 cm Delivery Sheath. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use. The devices are identical with the exception of a length and dilator tip angle change.