K080994

MAY 16 2008

510(k) Summary

Date Prepared	April 4, 2008
Submitter	AGA Medical Corporation 5050 Nathan Lane Plymouth, MN 55442
Contact	Michelle Nivala Sr. Regulatory Affairs Specialist
Telephone	763.531.3061
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E-mail	mnivala@amplatzer.com
Trade Name	AMPLATZER TorqVue Exchange System
Common Name	Catheter Delivery System
Device Classification	Class II, 21 CFR 870.1250 Catheter, Percutaneous
Product Code	DQY

Summary of Substantial Equivalence

The design, materials and performance of the AMPLATZER TorqVue Exchange System are substantially equivalent to the following predicate device:

- AMPLATZER TorqVue Delivery System – K072313 cleared November 2, 2007.

Device Description

The AMPLATZER TorqVue Exchange System is a sterile, single use device comprised of a delivery sheath, dilator, loader, hemostasis valve, delivery cable and vise. The system components are identical to the AMPLATZER TorqVue Delivery System, with the exception of the dilator, which incorporates an enlarged inner lumen for passage over a delivery cable. The Exchange System is available in two distal end curvatures: 180° and 45°.

Indications for Use

The AMPLATZER TorqVue Exchange System is intended for removal of an AMPLATZER Delivery Sheath and subsequent exchange for an AMPLATZER Delivery Sheath of equal or larger diameter.

Technological Characteristics

The design, materials, performance and packaging materials are substantially equivalent or identical to the predicate device referenced.

Summary of Testing

Device verification testing is presented to demonstrate the AMPLATZER TorqVue Exchange System meets established performance criteria and to support equivalency to the predicate device. Visual, performance and compatibility testing was completed. All design and compatibility requirements were met.

Biocompatibility testing consistent with ISO 10993-1: "Biological Evaluation of Medical devices – Part 1: Evaluation and Testing" is also presented.

The AMPLATZER TorqVue Exchange System will continue to be sterilized using a validated ETO sterilization process.

Conclusion

AGA Medical Corporation considers the AMPLATZER TorqVue Exchange System to be substantially equivalent to legally marketed predicate devices through the data and information presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2008

AGA Medical Corporation
c/o Ms. Michelle Nivala
Senior Regulatory Affairs Specialist
5050 Nathan Lane North
Plymouth, MN 55442-3209

Re: K080994
Trade Name: Amplatzer Torqvue Exchange System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY,
Dated: April 8, 2008
Received: April 7, 2008

Dear Ms. Nivala:

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.

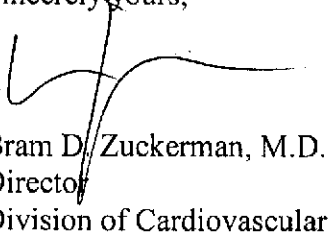
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 Biometrics' (OSB) 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 Statement

510(k) Number: K080994

Device Name: AMPLATZER TorqVue Exchange System

Indications for Use: The AMPLATZER TorqVue Exchange System is intended for removal of an AMPLATZER Delivery Sheath and subsequent exchange for an AMPLATZER Delivery Sheath of equal or larger diameter.

Prescription Use ___X___ **AND/ 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)

(Division Sign-Off)
Division of Cardiovascular Devices

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