

JUL 1 2 2000

2. Summary of Safety and Effectiveness

Sponsor: AGA Medical Corporation
682 Mendelssohn Avenue
Golden Valley, MN 55427

Contact person: Jodi L. Locher
Regulatory Affairs Manager

Submission Date: October 1, 1999

Common/Usual Name: Balloon Dilatation Catheter

Trade/Proprietary name: AMPLATZER® Sizing Balloon

Classification Name: AGA Medical Corporation believes the proposed device can be described by the following device classification names:

- Catheter, Percutaneous (870.1250)
- Catheter, Balloon Type (878.4200)

Device Classification: AGA Medical believes the proposed device is classified as a Class II device under:

- 74 DQY
- 79 GBA

Device Description: The AMPLATZER® Sizing Balloon is a 7F double lumen balloon catheter made from radiopaque nylon. The balloon is compliant and made from a very thin stretchable plastic membrane. The balloon-carrying segment is angled to 45° to the shaft providing a more or less right-angled position in relation to the atrial septum.

Intended Use: The AMPLATZER® Sizing Balloon is intended for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

Substantial Equivalence: The AMPLATZER® Sizing Balloon is equivalent in design to currently marketed balloon catheters used for temporary vessel occlusion.

The intended use is equivalent to the Cordis Corporation STABILIZER Marker Wire and the WIZDOM Marker Wire (K962765).

Safety and Performance: The following in vitro functional tests were performed on the AMPLATZER Sizing Balloon:

- Calculation of Inflation/Deflation Time, cc, Leakage and Burst Testing
- Pull Test - Bifurcation and Port Tubing
- Pull Test - Bifurcation and Shaft
- Animal Testing

In addition the following Biocompatibility Testing was performed:

- Hemocompatibility
- Cytotoxicity
- Dermal Sensitization
- Intracutaneous Injection
- Systemic Toxicity
- Pyrogenicity

Statement of Equivalence: The AMPLATZER® Sizing Balloon is substantially equivalent in product design and packaging to currently marketed balloon catheters used for temporary vessel occlusion. The proposed device is substantially equivalent in intended use (as a measurement tool with incorporation of marker bands) to the STABILIZER and WIZDOM Marker Wires currently marketed by Cordis Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 12 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jodi Raus
Regulatory Affairs Manager
AGA Medical Corporation
682 Mendelssohn Avenue
Golden Valley, MN 55427

Re: K993248
Amplatzer® Sizing Balloon
Regulatory Class: II (Two)
Product Code: MJN
Dated: June 12, 2000
Received: June 14, 2000

Dear Ms. Raus:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Jodi Raus

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

for

Enclosure

510 (k) NUMBER (IF KNOWN): K993248

DEVICE NAME: AMPLATZER® Sizing Balloon

INDICATIONS FOR USE:

The AMPLATZER® Sizing Balloon is indicated for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter-Use
(Division Sign-Off) (Optional Format 1-2-96)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____