K071327

510(k) Summary of Safety and Effectiveness

AUG 10 2007

Submitter

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Contact

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Date

May 10, 2007

Device

- Trade Name: MEMO 3D™ Semirigid Annuloplasty Ring
- 21 CFR 870.3800: Annuloplasty Ring
- Product Code: KRH – Class II – Special Controls
- Medical Specialty: Cardiovascular

Predicate Devices

- K926138: Baxter Healthcare Corporation Carpentier-Edwards Physio Annuloplasty Ring
- K970375 and K021051: Carbomedics AnnuloFlo™ System
- K023185: Carbomedics AnnuloFlex™ Annuloplasty System

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510(k) Summary of Safety and Effectiveness, Continued

Indications for Use

The MEMO 3D™ device is intended for correction of mitral insufficiencies or steno-insufficiences.

The use of the MEMO 3D™ device is indicated for correction of congenital or acquired mitral insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the device on its own. For type II insufficiencies, characterized by valve prolapse sustained by elongation/breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterized by partially immobilized leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

Contra-indications

The annuloplasty rings should not be used in the case of:

- Severe organic lesions with retraction of chordae tendinae
- Congenital malformations with limited valvular tissue
- Extensive calcification of valve leaflets
- Evolving bacterial endocarditis

Device Description

The MEMO 3D™ Semirigid Annuloplasty Ring is supplied as a sterile, non-pyrogenic, non-ferromagnetic ring pre-mounted on a disposable holder. The annuloplasty ring is manufactured by embedding a metallic inner core with medical grade silicone. The resulting silicone sheath, around the metallic core, is then encased within a tubular knitted fabric coated with Carbofilm™, which is a thin layer of turbostratic carbon. The fabric is then sewn along its length with Carbofilm™ coated polyester thread.

The annuloplasty ring is attached to the disposable holder to maintain the shape of the ring during implantation and allow for measured plications of the mitral annulus. Suture guides are present on the holder to aid the surgeon during ring placement.

The MEMO 3D™ annuloplasty ring is available in sizes 24mm through 38mm in two millimeter increments. A complete set of accessory instrumentation is to be available separately to properly size the annulus and implant the annuloplasty ring.

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510(k) Summary of Safety and Effectiveness, Continued

Technological Characteristics

The MEMO 3D™ Semirigid Annuloplasty Ring is considered to be substantially equivalent in technological characteristics and intended use to the predicate devices. Equivalency is supported by multiple characteristics, including:

- Intended use
- Anatomical site for implantation
- Product labeling
- Physical characteristics
- Target population
- Performance testing
- Safety characteristics

Non-Clinical Testing

Testing demonstrated that the MEMO 3D™ Semirigid Annuloplasty Ring is substantially equivalent to the predicate devices for repair of the mitral valve. Non-clinical testing included: ultimate tensile strength, suture pull-out, rigidity determination, computational stress analysis, fatigue and durability testing, corrosion resistance, biocompatibility, sterilization validation, pyrogenicity, and shelf-life.

Conclusion

The MEMO 3D™ Semirigid Annuloplasty Ring has been demonstrated as safe and effective for its intended use. With respect to intended use and technological characteristics, the MEMO 3D™ Semirigid Annuloplasty Ring is substantially equivalent to the legally marketed predicate devices.

K071327

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2007

Sorin Biomedica Cardio S.R.L.
C/O Heather Crawford, RAC
Project Manager, Regulatory Affairs
Carbomedics, Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K071327
Trade/Device Name: MEMO 3D™ Semirigid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: May 10, 2007
Received: May 11, 2007

Dear Ms Crawford:

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.

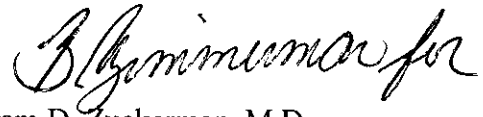
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K071327

Device Name: MEMO 3D™ Semirigid Annuloplasty Ring

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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
510(k) Number K071327