K042734

DEC 17 2004

510(K) SUMMARY

(as required by 21 CFR 807.92)

A. Submitters Information

Submitter's Name and Address:

St. Jude Medical, Inc.
Cardiac Surgery Division
One Lillehei Plaza
St. Paul, MN 55117

Contact Name

William McKelvey, RAC
Regulatory Affairs Specialist
St. Jude Medical, Inc.
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Submission Prepared

September 30, 2004

B. Device Information

Proprietary Name:

SJM™ Rigid Saddle ring
model RSAR-(size)

Common or Usual Name:

Rigid Annuloplasty ring,
Mitral Repair Ring

Classification:

Class II per 21 CFR 870.3800,
Annuloplasty rings

Predicate Device:

K032250-Edwards Lifesciences GeoForm™ annuloplasty ring model 4200 (Carpentier-McCarthy-Adams IMR-ETlogix annuloplasty ring model 4100)

Device Description:

The SJM™ Rigid Saddle Ring assembly consists of a rigid core machined from titanium covered with a double velour polyester fabric with a sewing cuff created for suturability. The ring is mounted on a holder and placed in a dual barrier package system. The package system is then steam sterilized. The SJM™ Rigid Saddle Ring is available in sizes 24mm-34mm (even sizes). Sizing is based on the inter-commissural distance as indicated by the commissure markers placed on the ring.

Intended Use:

The SJM™ Rigid Saddle Ring is indicated for use to correct annular dilation, increase leaflet coaptation, and prevent further dilatation of the mitral valve annulus caused by diseased states such as degenerative disease, rheumatic disease, ischemia or vascular disease. The combination of prosthetic ring with valvuloplasty may be used in all acquired or congenital mitral insufficiencies with dilation and deformation of the fibrous mitral annulus.

For mitral insufficiencies with no subvalvular lesions and normal valvular movements, prosthetic ring implant alone may be sufficient. However, annuloplasty ring implant along with mitral valvuloplasty repair must be considered for insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae and for insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae tendineae, or chordal hypertrophy.

C. Comparison of Required Technological Characteristics

SJM considers the SJM™ Rigid Saddle Ring to be substantially equivalent in technological characteristics (e.g. design and materials) and intended use to the predicate devices. The table below is a comparison of the equivalency characteristics between the SJM™ Rigid Saddle Ring and the predicate device.

Characteristic	Equivalency
a. Product Labeling	Substantially Equivalent
b. Intended Use	Substantially Equivalent
c. Physical Characteristics	Substantially Equivalent
d. Anatomical Sites	Identical
e. Target Population	Substantially Equivalent
f. Performance Testing	Substantially Equivalent
g. Safety Characteristics	Substantially Equivalent

D. Summary of Non-Clinical Tests

The following performance testing was conducted;

- Ring Tensile Strength
- Ring compressive Strength
- Suture Pullout Test
- Needle Penetration Test

- Computational Structural Analysis
- Holder Evaluation
- Assembled Ring/Holder Evaluation
- MR Safety
- Package Shelf Life Evaluation
- Manufacturing Process validation
- Biocompatibility Evaluation
- Chemical and Morphological Evaluation
- Sterilization Validation
- Bioburden
- Pyrogenicity

Conclusion

SJM has demonstrated that the SJM™ Rigid Saddle Ring is safe and effective for the intended use. The SJM™ Rigid Saddle Ring is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

St. Jude Medical, Inc.
c/o Mr. William McKelvey
Regulatory Affairs Specialist
Cardiac Surgery Division
One Lillehei Plaza
St. Paul, MN 55117

Re: K042734
SJM™ Rigid Saddle Ring Model RSAR-(size)
Regulation Number: 21 CFR 870.3800
Regulation Name: Rigid Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: September 30, 2004
Received: October 1, 2004

Dear Mr. McKelvey:

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 Office of Compliance at (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna R. Lechner

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

Enclosure

U.S. Food and Drug Administration – Center for Devices and Radiological Health

510(k) Number (if known): K042734

Device Name: SJM™ Rigid Saddle Ring

Indications For Use

The SJM™ Rigid Saddle ring is indicated for use to correct annular dilation, increase leaflet coaptation, and prevent further dilatation of the mitral valve annulus caused by diseased states such as degenerative disease, rheumatic disease, Ischemia or vascular disease. The combination of prosthetic ring with valvuloplasty may be used in all acquired or congenital mitral insufficiencies with dilation and deformation of the fibrous mitral annulus.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane D. Lachmann

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042734