K014037

JAN 0 4 2002

510(K) SUMMARY

(as Required by 21 CFR § 807.92)

A. Submitters Information

Submitter's Name: St. Jude Medical, Inc
Cardiac Surgery Division

Address: St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, MN 55117

Contact Name William McKelvey
Regulatory Affairs Coordinator
St. Jude Medical, Inc.
Bus : (651) 415-7029
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Submission Prepared: December 6, 2001

B. Device Information

Proprietary Name: SJM® Seguin annuloplasty ring (Seguin ring) model SARP-(size)

Common or Usual Name: Annuloplasty Ring
Valvulplasty Ring
Mitral Valve Support Ring

Classification: Pre-amendment Class II CFR § 870.3800 Cardiovascular Prosthetic Devices, Annuloplasty Ring (revised April 10, 2001)

Predicate Device: St. Jude Medical considers The Seguin ring, model SARP to be substantially equivalent to the Seguin ring model SAR.

Device Description The Seguin ring is a semi-rigid ring fabricated from an untra-high molecular weight polyethylene (PE) core surrounded by a polyester sewing ring. providing a means for attaching the ring to the heart annulus as well as a suitable surface for tissue ingrowth.

Intended Use: The Seguin ring is indicated for use in repair of diseased or damaged mitral heart valves that are determined by the physician to be repairable and do not require replacement.

C. Comparison of Required Technological Characteristics

SJM considers the Seguin ring, model SARP to be substantially equivalent in configuration, function and intended use to the Seguin ring, model SAR. The table below is a comparison of the equivalency characteristics between the two devices.

Characteristic	Equivalency
a. Product Labeling	Substantially Equivalent
b. Intended Use	Identical
c. Physical Characteristics	Different (Holder and Handle only)
d. Anatomical Sites	Identical
e. Target Population	Identical
f. Performance Testing	Substantially Equivalent
g. Safety Characteristics	Substantially Equivalent

D. Summary of Non-Clinical Tests

The testing for the Seguin ring model SAR (predicate) is included in the premarket notification (K961246). The following tests have been performed on the Seguin ring model SARP to insure substantial equivalence with the predicate.

New Holder/Handle Configuration

1. Physical Testing
   - Holder to Handle connection
   - Holder assembly
   - Ring assembly to holder

2. Microbiological Testing
   - Biocompatibility
   - Additional Evaluation of Routine Testing
   - Sterility Assurance
   - EtO Residual Evaluation

3. Manufacturing Process Validation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2002

Mr. William McKelvey
Regulatory Affairs Coordinator
St. Jude Medical, Inc.
One Lillehei Plaza
St. Paul, MN 55117

Re: K014037
Trade Name: SJM® Seguin Annuloplasty Ring, Model SARP(size)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: December 6, 2001
Received: December 7, 2001

Dear Mr. McKelvey:

This letter corrects our substantially equivalent letter regarding the SJM® Seguin Annuloplasty Ring dated January 4, 2002. Our letter incorrectly referred to your Model name as SAR-M. This is an error. The Model name has been corrected to SARP.

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.

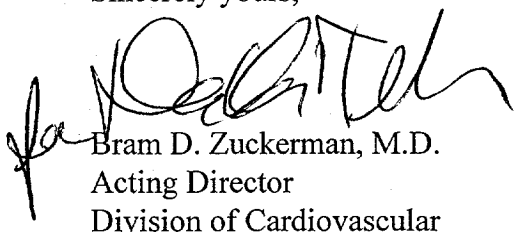
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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). 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,



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

Enclosure

510(k) Number (if known): K014037

Device Name: **SJM® Seguin annuloplasty ring**

Indications for Use:

The SJM® Seguin annuloplasty ring is indicated for use in the repair of a mitral valve that is diseased or damaged due to acquired or congenital processes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014037

Prescription Use X or Over-The-Counter Use ____

Per 21 CFR 801.109) Optional Format 1-2-96)