

510(k) Summary

(As required by 21 CFR 807.92)

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A. Submitter Information

Submitter's Name: St. Jude Medical Division (SJMD)

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

Contact Person: Jonas A. Runquist

Telephone Number: (612) 483-2000

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B. Device Information

Proprietary Name: SJM® Seguin Annuloplasty Ring Model SAR-M

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

Classification Name: Pre-amendment Class III CFR §870.3800
Cardiovascular Prosthetic Devices, Annuloplasty Ring

Predicate Device: St. Jude Medical considers the Seguin Annuloplasty ring to be "substantially equivalent" to the Carpentier-Edwards Physio™ annuloplasty ring manufactured by Baxter Healthcare Corporation. The Physio annuloplasty ring was previously found by the Food and Drug Administration to be substantially equivalent to the Carpentier-Edwards ring which was marketed prior to May, 1976.

Device Description: The Seguin Annuloplasty Ring is a semi-rigid annuloplasty ring fabricated from an ultra-high molecular weight polyethylene (PE) core surrounded by

a custom Dialine® polyester sewing ring . The PE core is covered with a knitted polyester material providing a means for attaching the ring to the heart annulus as well as a suitable surface for tissue ingrowth.

Intended Use:

The Seguin Annuloplasty 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. The Seguin Annuloplasty Ring provides support to the mitral heart valve restricting expansion of the annulus.

C. Comparison of Required Technological Characteristics

SJM considers the Seguin Annuloplasty Ring substantially equivalent in general configuration, function and intended use to the Carpentier-Edwards Physio™ annuloplasty ring. The table below addresses equivalency characteristics for the Seguin Annuloplasty Ring and the Physio™ annuloplasty ring. Each equivalency characteristic is then further addressed.

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

Product Labeling

Product labeling provided with the Seguin Annuloplasty Ring and the Physio™ annuloplasty ring are substantially equivalent as both devices provide similar Indications for Use, contraindications, warnings, precautions, etc.

Intended Use

The intended use for the Seguin Annuloplasty Ring and the Physio™ annuloplasty ring are identical. Both devices are intended for the repair of diseased or damaged mitral valves determined by the Physician to be repairable.

Physical Characteristics

The physical characteristics of the Seguin Annuloplasty ring and the Physio™ annuloplasty ring are substantially equivalent as both devices are kidney shaped to match the mitral heart annulus. Both devices utilizes a core that provides a combination of flexibility and rigidity. The Seguin Annuloplasty Ring utilizes a polymer core and the Physio™ annuloplasty ring utilizes a core of metal bands to provide the semi-flexible properties. Both devices are covered in polyester fabric providing a means to attach the device to the heart annulus. The Seguin annuloplasty ring is available in mitral sizes 26mm - 40mm and the Physio™ annuloplasty ring is available in mitral sizes 24mm - 40mm. Both devices utilize a set of sizing obturators to select the proper size of prosthesis.

Anatomical Sites

Both the Seguin Annuloplasty Ring and the Physio™ annuloplasty ring are intended for use in the mitral valve.

Target Population

The target population for the Seguin Annuloplasty Ring and the Physio™ annuloplasty ring are identical. Both devices are targeted for patients of all ages, etc. with diseased or damaged mitral valves caused by acquired congenital processes resulting in mitral insufficiency and or stenosis.

Performance Testing

Performance testing on the Seguin Annuloplasty Ring has demonstrated that the prosthesis is substantially equivalent to the Physio™ annuloplasty ring. Animal testing (and clinical evaluations) have clearly demonstrated that the Seguin Annuloplasty Ring, like the Physio™ annuloplasty ring is capable of adequately repairing diseased or damaged mitral valves.

Safety Characteristics

Safety testing on the Seguin Annuloplasty Ring has demonstrated that the prosthesis is substantially equivalent to the Physio™ annuloplasty ring. *in-vitro* testing has illustrated that the Seguin Annuloplasty Ring, like the Physio™ annuloplasty ring is capable of withstanding stresses without failure well beyond those that may be experience *in-vivo*. Biocompatibility testing has also established that the Seguin ring like the Physio™ annuloplasty ring, is biocompatible and non-toxic.

D. Summary of Nonclinical Tests

The following outlines the testing performed to demonstrate substantial equivalence to the Physio™ annuloplasty ring.

1. Evaluation of the mitral annulus to examine deflections of the Seguin Annuloplasty Ring based on literature references.

A thorough review of the literature was performed to obtain estimates for physiological loads that may be placed on a cardiovascular prosthesis such as an annuloplasty ring *in-vivo*. The literature indicates that a worst case physiological load may be approximately 1.8 Lbs. and 200 mm Hg. The literature states that the maximum orifice reduction based on these loads is approximately 10% for a flexible annuloplasty ring, and 2.9% for a rigid annuloplasty ring. SJM utilized the 10% value for the flexible ring as the worst case condition in evaluating structural integrity of the Seguin Annuloplasty Ring. In reality, the Seguin Annuloplasty Ring like the Physio™ annuloplasty ring is a semi-rigid prosthesis and would be expected to have an orifice reduction of between 10% and 2.9% during a severe cardiac cycle.

2. Theoretical failure analysis

- a. Stress magnitudes
- b. Stress location

The Computational Structural Analysis addressed the structural stress magnitudes and stress locations on the Seguin Annuloplasty Ring. The results of this testing demonstrated that the expected worst case physiological loads based on literature references are less than half the force required to yield the Ultra High Molecular Weight polyethylene core of the Seguin Annuloplasty Ring. This testing has demonstrated that the Seguin Annuloplasty Ring has similar safety characteristics as the Physio™ annuloplasty ring.

3. Physical testing

- a. Compressive failure mechanism based on theoretical loads and deflections

Compressive testing was designed to demonstrate that the force required to reduce the area of the Seguin Annuloplasty Ring by 10% (representing extreme conditions) did not result in damage or compromise the performance of the prosthesis. Data

indicates that the 26mm ring (smallest) represents worst case conditions as it requires the greatest load to reduce the orifice of the ring by 10%. Decreased loads are required to achieve the 10% orifice reduction for the larger ring sizes.

b. Tensile failure mechanism based on theoretical loads and deflections

Tensile tests were performed to illustrate that the yield strength and the ultimate tensile strength of the Seguin Annuloplasty Ring are extremely high and are well above expected *in-vivo* stresses.

c. Suture pull out tests

The suture pull out test was designed to evaluate the potential of ring dehiscence with the Seguin Annuloplasty Ring as a result of sewing ring fabric failure. These tests investigated the strength of the hand sewn seam on the sewing ring as well as the tensile strength of the fabric. The strength of the sewing ring seam and fabric were evaluated by placing sutures through the sewing cuff and performing tensile or pull tests. This testing demonstrated that the hand sewn seam is stronger than the fabric as all sutures tore the fabric before failure of the seam occurred. The study also demonstrated that the strength of the fabric far exceeds the forces expected *in-vivo*.

The physical testing performed on the Seguin Annuloplasty Ring has demonstrated that it has similar safety characteristics as the Physio™ annuloplasty ring.

4. Biocompatibility testing

The materials used for the Seguin Annuloplasty Ring have an extensive clinical history with no adverse biocompatible response. The tests performed and the results are as follows:

Test	Result
USP Systemic Injection	Pass
USP Implantation (14 day) - Ultra High Molecular Weight Polyethylene	Pass
USP Implantation (14 day) - Polyester Fabric	Pass
Salmonella Mutagenicity Plate Assay (Ames Assay)	Pass
USP Intracutaneous Test	Pass
Guinea Pig Delayed Contact Sensitization Test	Pass
(Extracted in Cottonseed Oil)	
Guinea Pig Delayed Contact Sensitization Test	Pass
(Extracted in Sodium Chloride)	

USP Rabbit Pyrogen Test Pass
 Subchronic Toxicity with Histopathology (14 day) Pass

The biocompatibility tests were conducted at ViroMed Laboratories in Minneapolis MN, and were performed under Good Laboratory Practices per 21 CFR Part 58.

In addition to the biocompatibility tests performed above, physical testing, chemical testing, and animal implant tests were performed on Dialine polyester fabric by an outside expert. This testing was published in a scientific journal. (King, et. al: Evaluating the Dialine Vascular Prosthesis knitted from an alternative source of polyester yarns *Journal of Biomedical Materials Research*, Vol 29, 595-610 (1995)). The results of these tests demonstrated that the Dialine polyester fabric was essentially equivalent to Dupont based (Dacron®) polyester fabrics in terms of physical, chemical, and tissue response characteristics.

5. **Long term animal testing**
- a. **Surgical handling characteristics**
 - b. ***in-vivo* performance**
 - **Tissue in-growth properties**
 - **Macroscopic evaluations**
 - **Histological examinations**

Animal testing on the Seguin Annuloplasty Ring was designed to evaluate the performance of the prosthesis *in-vivo* for up to two years. Animals were monitored for evidence of excessive stenosis, regurgitation or other complications. Following explant, the annuloplasty rings were subjected to complete macroscopic, microscopic and histological examinations to assess the prosthesis for evidence structural failure and to evaluate healing characteristics. All results from the animal study were considered excellent.

The animal testing has demonstrated that the performance of the Seguin Annuloplasty Ring is similar to the Physio™ annuloplasty ring.