K072655

OCT 23 2007

510(k) Summary Information *Premarket Notification, Section 510(k)*	**Genesee Biomedical, Inc.** **SEPTEMBER 12, 2007**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

   Trade Name: ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Ring Model 800SR

   Common Name(s): Annuloplasty Ring

   Classification Name(s): Ring, Annuloplasty

2. **Establishment Name & Registration Number:**

   Name: **Genesee Biomedical, Inc.**
   Number: 1723241

3. **Classification(s):**

   Device Class: Class II
   Classification Panel: Cardiovascular Devices Panel
   Product Code(s): KRH

4. **Equivalent Predicate Device:**

   Genesee Biomedical Inc's. Sculptor® Semi-Rigid Mitral Annuloplasty Ring Model 605M (K905175). Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. **Device Description:**

   The ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Rings Model 800SR are implantable, Semi-Rigid, annular rings. The rings reduce and stabilize the atrioventricular annulus in patients undergoing mitral valve repair. The body of the ring is made of flat braided Polyester. The ring contains an MP35N wire stiffener in the lateral and posterior segments. The wire stiffener is contained within a close-coiled MP35N spring, the two ends of which are joined together by a miniature MP35N coupler in the mid-anterior segment. The entire circumferential of the annuloplasty ring is radiopaque. The rings are available in the following six sizes: 24mm, 26mm, 28mm, 30mm, 32mm 34mm, 36mm, 38mm and 40mm. The size refers to the lateral diameter of the stiffener band.

6. **Packaging:**

The ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Ring is supplied STERILE (sterilized by gamma radiation) and non-pyrogenic, mounted on a disposable holder, packaged in inner and outer Chevron style Tyvek/Polymylar peel pouches. The ring will remain sterile until at least the expiration date provided the package is unopened and undamaged.

7. **Indications for Use:**

The ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Rings are for use in those patients undergoing surgery of diseased or damaged mitral valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty rings provide support for the natural annulus and restrict expansion of the annulus

8. **Testing Summary:**

Testing included LAL, Sterility Validation, and Class VI Biocompatibility tests on the predicate device. Mechanical testing was carried out on complete modified rings and ring components. All test results were satisfactory.

9. **Applicant Name & Address:**

John T. M. Wright, Ph.D.
Genesee Biomedical, Inc.
1308 So Jason Street,
Denver, CO 80223
Phone (303) 777-3000 extension 111
Fax (303) 777-8866
Email jwright@geneseebiomedical.com

10. **Registration Number:**

1723241

11. **Company Contact:**

John Wright, Ph.D.
Genesee Biomedical, Inc.

12. **Submission Correspondent:**

John T. M. Wright, Ph D.
Chief Executive Officer
Genesee Biomedical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Genesee Biomedical, Inc
c/o John T. M. Wright Ph.D
Chief Executive Officer
1308 S. Jason Street
Denver, CO 80223-3408

Re: K072655
ATS Simulus™ Semi-Rigid Mitral Annuloplasty Ring Model 800SR
Regulation Number: 21 CFR 870.3800
Regulation Name: Ring, Annuloplasty
Regulatory Class: Class II (two)
Product Code: KRH
Dated: September 12, 2007
Received: September 24, 2007

Dear Dr. Wright:

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 (240) 276-0120. 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 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

510(k) Number : K072655

Device Name(s): **ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Ring Model 800SR**

Indications For Use:

The ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Rings Model 800SR are for use in those patients undergoing surgery of diseased or damaged mitral valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty rings provide support for the mitral annulus and restrict expansion of the annulus.

Prescription Use ____X____ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) (Optional format 1-2-96)

Donna R. Heckmeyer

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K072655