K093903

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

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

1. **Device Name:**

   Trade Name: ATS TRI-AD™ Semi-Flexible Tricuspid Annuloplasty Ring Model 900SFC

   Common Name(s): Annuloplasty Ring

   JUL 15 2010

   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. ATS SIMULUS® Semi-Flexible Tricuspid Annuloplasty Ring Model 800SR (K072655). Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. **Device Description:**

   The ATS TRI-AD™ Semi-Flexible Tricuspid Annuloplasty Rings Model 900SFC 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 the stiffener wire are fitted with miniature MP35N end caps at each trigone. These caps prevent the stiffener wire from poking through the end seam of the ring. The entire circumferential of the annuloplasty ring is radiopaque between trigones. The Rings are available in the following six sizes: 26mm, 28mm, 30mm, 32mm, 34mm, 36mm. The size refers to the inner major diameter of the ring.

6. **Packaging:**

The ATS TRI-AD™ Semi-Flexible Tricuspid 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 TRI-AD™ Semi-Flexible Tricuspid Annuloplasty Bands are for use in those patients undergoing surgery of diseased or damaged mitral valves in which the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for the natural annulus and restrict expansion of the annulus

8. **Testing Summary:**

Testing included LAL, Sterility Validation, and Class VI Biocompatibility had previously been carried out on a predicate device. The following mechanical tests were carried out on complete modified bands and ring components.

1. Tensile strength of flat Polyester tubular braid.
2. 4-0 Suture tensile test
3. Stiffener wire tensile strength.
4. Body implant suture pull out strength.
5. Stiffener retention seam penetration strength.
6. Finite Element Analysis (FEA) of the stress levels of stiffeners

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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 15 2010

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

Re: K093903
Trade Name: ATS TRI-AD™ Semi-Flexible Tricuspid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: June 14, 2010
Received: June 15, 2010

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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) K093903

Device Name: **ATS TRI-AD Semi-Flexible Tricuspid Annuloplasty Ring Model 900SFC**

Indications For Use:

The ATS TRI-AD™ Semi-Flexible Tricuspid Annuloplasty Rings Model 900SFC are for use in those patients undergoing surgery of diseased or damaged tricuspid 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 tricuspid annulus and restrict expansion of the annulus.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (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)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093903