K090428
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510(k) Summary Information *Premarket Notification, Section 510(k)*	**Genesee Biomedical, Inc.** **APRIL 30, 2007**

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

1. **Device Name:**
   Trade Name: ATS SIMULUS® Adjustable Flexible Annuloplasty Band Model 735 AC

   Common Name(s): Annuloplasty Ring

   MAY - 7 2009

   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. SIMULUS® Adjustable Flexible Annuloplasty Ring Model 735AF

   Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. **Device Description:**
   The ATS SIMULUS® Adjustable Flexible Annuloplasty Bands Model 735AC are implantable, adjustable flexible, annular bands (Figure II.1). The bands reduce and stabilize the atrioventricular annulus in patients undergoing mitral or tricuspid valve repair. The body of the band is made of tubular braided Polyester. The band contains circumferential flexible radiopaque markers. The entire circumference of the band is radiopaque.
   The bands are available in the following six sizes: 25 mm, 27 mm, 29 mm, 31 mm, 33 mm, 35 mm, 37mm and 39mm. The size refers to the equivalent inner circumference of the band, trigone to trigone.

6. Packaging:

The ATS SIMULUS® Annuloplasty Bands are supplied STERILE (sterilized by gamma radiation) and non-pyrogenic, packaged in inner and outer Chevron style Tyvek/Polymylar peel pouches. The rings will remain sterile until at least the expiration date provided the package is unopened and undamaged.

7. Indications for Use:

The ATS SIMULUS® Adjustable Flexible Annuloplasty Bands are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for the mitral or tricuspid 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:

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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

MAY - 7 2009

Genesee Biomedical, Inc.
John T.M. Wright, Ph.D., CEO
1308 S Jason Street
Denver CO 80223

Re: K090428
Trade/Device Name: ATS SIMULUS® Adjustable Flexible Annuloplasty Band Model 735AC
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: April 30, 2009
Received: May 1, 2009

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Indications for Use

510(k) Number (if known): K090428

Device Name: **ATS SIMULUS® Adjustable Flexible Annuloplasty Band Model 735AC**

Indications For Use:

The ATS SIMULUS® Adjustable Flexible Annuloplasty Bands Model 735AC are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for the mitral or 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090428