DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 12, 2016

Genesee Biomedical, Inc.
Woodrow Mathison
President and CEO
700 W. Mississippi Ave
Unit D-5
Denver, Colorado 80223-4509

Re: K161815
Trade/Device Name: FlexForm Annuloplasty Ring and FlexForm Annuloplasty Band
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: September 12, 2016
Received: September 13, 2016

Dear Mr. Mathison:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161815

Device Name
FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band

Indications for Use *(Describe)*
The FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band are indicated for use in 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 rings and bands provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band

Applicant	Genesee BioMedical, Inc. 700 W Mississippi Ave. Unit D-5 Denver, Colorado 80223-4509 Toll Free: 1-800-786-4890
Contact Person	Woodrow G. Mathison, President and CEO 700 W Mississippi Ave. Unit D-5 Denver, Colorado 80223-4509 wmathison@geneseebiomedical.com
Date Prepared	October 6, 2016
Trade Name	FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band
Common or Usual Name:	Annuloplasty Ring or Annuloplasty Band
Classification	Class II: Special Controls Regulation Number: 21 CFR 870-3800
Product Code	KRH
Review Panel	Cardiovascular
Predicate Device	The subject device is substantially equivalent to the ATS Simulus Annuloplasty Ring Model 700FF and the ATS Simulus FC Annuloplasty Ring Model 700FC.
Device Description	The FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band are fully flexible annular rings and bands designed to reduce and stabilize the valve annulus in patients undergoing mitral or tricuspid repair. The rings and bands are made of braided polyester fabric. The ring and band contain a circumferential flexible radiopaque marker. The internal radiopaque marker provides radiographic visualization along the entire circumference. The rings and bands are available in nine sizes: 24 mm; 26 mm; 28 mm; 30 mm; 32 mm; 34 mm, 36 mm, 38 mm and 40 mm. The size refers to the inner circumference between the green suture markers

	nearest the anterior location of the ring and band. FlexForm™ Sizers, Model FRBS, are used to determine the correct size of the ring or band. The differences between the ring and band are as follows: The FlexForm™ Ring is a complete annular ring. Five markers are provided on the ring; two markers indicate the approximate location of the trigones; three additional markers are provided as an aid to suture placement in the posterior section. The FlexForm™ Band is a partial ring, without an anterior segment. The key dimensions are the same as the FlexForm Annuloplasty Ring, except for the absence of the anterior segment. Five markers are provided on the band; two markers indicate the approximate location of the trigones; three markers are provided as an aid to suture placement in the posterior section. The choice of ring or band is based on surgeon preference.
Indication for Use	The FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band are indicated for use in 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 rings and bands provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.
Principle and Mechanism of Operation	The FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.
Functional and Safety Testing	To verify that device design meets functional and performance requirements, representative samples of the devices underwent testing in accordance with applicable standards and guidance. These data provide an acceptable assurance of the safety and effectiveness of the FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band and demonstrate the devices are equivalent to the predicates.
Comparative Technology Characteristics	A comparison of the characteristics of the proposed device and the predicate devices shows the FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band to have the same technological characteristics as the predicate devices that have received 510(k) clearance. Equivalence is based upon intended use, indications for use, principles of operation and fundamental technology. Both devices are intended

	for use in surgical repair of mitral and tricuspid heart valves. Both devices have similar or identical structure, materials of composition, sterilization method, size range, sizing accessories, packaging and site of application in the body.
Non-Clinical Tests Submitted	Performance testing was performed to support substantial equivalence, including: Tensile strength of ring body materials Tensile strength of construction sutures Suture pull-out testing
Conclusion	Genesee BioMedical, Inc. considers the FlexForm™ Annuloplasty Ring and FlexForm™ Annuloplasty Band to be equivalent to the predicate devices. This conclusion is based upon the fact that the devices have an equivalent intended use, and there are no differences that raise new questions of safety and effectiveness.