July 25, 2025

Genesee Biomedical Inc
James Cross
Quality Assurance Manager
700 W. Mississippi Ave Unit D-5
Denver, Colorado 80223

Re: K250859
Trade/Device Name: TransForm™ McCarthy Mitral Annuloplasty Ring (TF)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: June 26, 2025
Received: June 26, 2025

Dear James Cross:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JULIE B. MACKEL -S

For

Samuel Raben, PhD
Acting Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250859

Device Name
TransForm™ McCarthy Mitral Annuloplasty Ring (TF)

Indications for Use *(Describe)*
TransForm™ McCarthy Mitral Annuloplasty Ring (TF) is indicated for use in patients undergoing surgery for diseased or damaged mitral valves. The ring provides support for and restricts expansion of the mitral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K250859

510(k) Summary

Prepared on: 2025-06-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Genesee Biomedical Inc
Applicant Address	700 W. Mississippi Ave Unit D-5 Denver CO 80223 United States
Applicant Contact Telephone	303-777-3000
Applicant Contact	Mr. James Cross
Applicant Contact Email	jcross@geneseebiomedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TransForm™ McCarthy Mitral Annuloplasty Ring (TF)
Common Name	Annuloplasty ring
Classification Name	Ring, Annuloplasty
Regulation Number	870.3800
Product Code(s)	KRH, DTI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232599	TransForm™ McCarthy Annuloplasty Ring (TF)	KRH

Device Description Summary

21 CFR 807.92(a)(4)

The TransForm™ McCarthy Mitral Annuloplasty Ring is an implantable, semi-rigid annuloplasty ring for mitral valve repair with the stiffened portions at the anterior and posterior segments. The ring is flexible at the commissure regions to allow physiological movement of the annulus. Stiffener placement allows the ring to maintain its "D" saddle shape during systole and a flat planar "O" shape in diastole. The stiffeners consist of MP35N 0.71 mm diameter (polished and formed) alloy. An elastic silicone core and braided polyester fabric form the ring body. The TransForm™ Annuloplasty Ring has four green radial markers: two markers at the left and right trigones and two markers at the mid-anterior and mid-posterior. The ring conforms to the natural mitral annulus throughout the cardiac cycle. The interrupted stiffeners within the silicone core provide semi-rigid elastic flexibility. Elasticity of the "D" to "O" or circular transformation, accommodates remodeling of the annulus, while creating inward forces to maintain circular annular geometry against physical expansion. The size range of TransForm™ is from 24mm to 40mm with 2mm increments. Size refers to the internal CC diameter of the ring. Rings are intended to be implanted on the patient's mitral annulus to reduce and stabilize the annulus.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

TransForm™ McCarthy Mitral Annuloplasty Ring is indicated for use in patients undergoing surgery for diseased or damaged mitral valves. The ring provides support for and restricts expansion of the mitral annulus.

Indications for Use Comparison

21 CFR 807.92(a)(5)

A comparison of the characteristics of the proposed device and the predicate and/or reference device show that there are no differences between the subject device and the predicate device with respect to clinical aspects, indications and intended use. Both devices have the same principle and mechanism of operation. The TransForm™ McCarthy Mitral Annuloplasty Ring is determined to be substantially equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Technological aspects were assessed for substantial equivalence. The subject device and the predicate devices have the same size, shape and similar material composition. The subject device, the TransForm™ McCarthy Annuloplasty Ring, will be manufactured under equivalent conditions as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Structural Analysis
Braid tensile strength
Radial Seam tensile test
Suture pull out/tensile strength
Sterilization validation per ISO 11137-1

Biocompatibility testing was completed as follows:
-Cytotoxicity per ISO 10993-5
-Material-Mediated Pyrogenicity per USP <151>
-Sensitization per USP 10993-10
-Intracutaneous Irritation per ISO 10993-23
-Acute Systemic Toxicity per USP 10993-11
-12 week Implantation test per USP 10993-6
-Hemocompatibility per ISO 10993-4
--Hemolysis per ASTM F756
--Leukocyte and Platelet Assay per ASTM F2888
--Partial Thromboplastin Time per ASTM F2382
--Compliment Activation Assay per ISO 10993-4

Chemical characterization testing per ISO 10993-18 and toxicological risk assessment per ISO 10993-17 was completed to address the following:
-Toxicity (sub-acute/sub-chronic & chronic)
-Genotoxicity
-Carcinogenicity

Genesee BioMedical, Inc. considers the TransForm™ McCarthy Mitral Annuloplasty Ring to be substantially equivalent to the predicate device. This conclusion is based upon the fact that devices have an identical intended use, and there are no clinical, technical or biological differences, in performance testing that raise new questions of safety and effectiveness. Nonclinical testing demonstrates that the construction braid tensile strength exceeds the pass/fail criteria; that the worst cases for each specific stiffener size have higher safety factors than the absolute worst case used for evaluation in this FEA and that the braid material used to construct the TransForm™ McCarthy Mitral Annuloplasty Ring provides a suture pullout strength that exceeding the minimum pass/fail criteria.