October 6, 2020

Genesee BioMedical, Inc
Woodrow Mathison
President and CEO
700 W Mississippi Ave, Unit D5
Denver, Colorado 80223-4509

Re: K202253
Trade/Device Name: TruForm™ Sievers Annuloplasty Ring, Model TRH
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: August 10, 2020
Received: August 11, 2020

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Jaime Raben
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202253

Device Name
TruForm Sievers Annuloplasty Ring, Model TRH

Indications for Use *(Describe)*
The TruForm Sievers Annuloplasty Ring is indicated for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.

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.

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510(k) Summary
TruForm™ Sievers Annuloplasty Ring

Applicant	Genesee BioMedical, Inc. 700 W Mississippi Ave. Unit D5 Denver, Colorado 80223-4509
Contact Person	Woodrow G. Mathison, President and CEO wmathison@geneseebiomedical.com Phone: 303-777-3000 Fax: 303-777-8866
Date Prepared	October 1, 2020
Trade Name	TruForm™ Sievers Annuloplasty Ring Model TRH
Common or Usual Name	Annuloplasty Ring
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 NeoForm™ Annuloplasty Ring, Model 4200 (K190506)
Reference Devices	K161815 - FlexForm Annuloplasty Ring K905175 - Sculptor Annuloplasty Ring K072655 - Simulus Annuloplasty Ring
Device Description	The TruForm™ Sievers Annuloplasty Ring, Model TRH is a semi-flexible implantable annuloplasty ring designed to reduce and stabilize the valve annulus in patients undergoing mitral repair. The inner core of the ring is made of a titanium alloy. Silicone covers the inner core and a sewing cuff made of braided polyester encompasses the ring. Three points of the ring are marked with polyester suture to aid in suture placement for implantation. The ring is available in ten (10) sizes: 24 mm; 26 mm; 28 mm; 30 mm; 32 mm; 34 mm; 36 mm; 38 mm; 40 mm; and 42 mm.

Indications for Use:	The TruForm™ Sievers Annuloplasty Ring is indicated for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.
Principle and Mechanism of Operation	The TruForm Sievers Annuloplasty Ring provides support for the mitral valve and restricts 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 demonstrate the device is equivalent to the predicate and/or reference device.
Comparative Technology Characteristics	A comparison of the characteristics of the proposed device and the predicate and/or reference device show the TruForm™ Sievers Annuloplasty Ring to have the same technological characteristics as the predicate device that has 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 heart valves. The subject and predicate device have similar or identical materials of composition, size range, sizing accessories and site of application in the body. Changes between the device and predicate include minor modifications to the shape and the addition of six (6) ring sizes.
Non-Clinical Tests Submitted	Testing was performed to support substantial equivalence, including: Biocompatibility Sterilization Computational Finite Element Analysis (FEA) Tensile strength of ring materials Suture pull-out testing MRI Compatibility Packaging Shelf-life

Conclusion	Genesee BioMedical, Inc. considers the TruForm™ Sievers Annuloplasty Ring to be equivalent to the predicate device. This conclusion is based upon the fact that the devices have an equivalent intended use, and there are no differences that raise different questions of safety and effectiveness.