May 26, 2023

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

Re: K230679
Trade/Device Name: WellsForm Tricuspid Annuloplasty Band (WF)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH, DTI
Dated: March 10, 2023
Received: March 13, 2023

Dear Woodrow 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,

Julie B. Mackel -S

For

Jennifer Bastijanic
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230679

Device Name
WellsForm Tricuspid Annuloplasty Band (WF)

Indications for Use *(Describe)*
WellsForm Tricuspid Annuloplasty Band is indicated for the surgical reconstruction or remodeling of diseased or damaged tricuspid valves. The band provides support for and restricts expansion of the tricuspid 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.

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510(k) Summary

Prepared on: 2023-05-25

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. Woodrow Mathison
Applicant Contact Email	wmathison@geneseebiomedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	WellsForm Tricuspid Annuloplasty Band (WF)
Common Name	Annuloplasty ring
Classification Name	Ring, Annuloplasty
Regulation Number	870.3800
Product Code	KRH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K093903	Tri-Ad Semi-Flexible Annuloplasty Ring Model 900SFC	KRH

Device Description Summary

21 CFR 807.92(a)(4)

The WellsForm™ Tricuspid Annuloplasty Band is an implantable ring intended for surgical repair of the tricuspid heart valve. WellsForm Tricuspid Annuloplasty Band is indicated for the surgical reconstruction or remodeling of diseased or damaged tricuspid valves. The band provides support for and restricts expansion of the tricuspid annulus.

The WellsForm™ Tricuspid Annuloplasty Band consists of a braided textile polyester body with a semi-rigid (stiffened) portion at the septal and aortic segments. The flexible section runs from the aortic segment, about half of the anterior leaflet, to the posteroseptal commissure to help remodel and stabilize the enlarged portion of the tricuspid annulus found in patients with functional tricuspid regurgitation.

The size range of the WellsForm Tricuspid Annuloplasty Band is from 26mm to 36mm in 2mm increments (sizes: 26, 28, 30, 32, 34, and 36).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

WellsForm Tricuspid Annuloplasty Band is indicated for the surgical reconstruction or remodeling of diseased or damaged tricuspid valves. The band provides support for and restricts expansion of the tricuspid 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 WellsForm Tricuspid Annuloplasty Band 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 similar size, shape, and material composition. The subject device, the WellsForm Tricuspid Annuloplasty Band, will be manufactured under equivalent conditions as the predicate device.

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

The following non-clinical and/or clinical tests were completed on the WellsForm Tricuspid Annuloplasty Band:

Computational Structural Analysis (SFEA)
Braid tensile strength
Suture pull out/tensile strength
Sterilization Validation
Cytotoxicity
Pyrogenicity

Due to the substantially equivalent materials and process of the predicate and reference devices, the following non-clinical and/or clinical tests were not completed on the WellsForm Tricuspid Annuloplasty Band and the results of the previously approved devices were leveraged:

Sensitivity
Irritation
Systemic Toxicity
Genotoxicity
Implantation Testing
Haemocompatibility
Carcinogenicity
Packaging and Shelf Life Study

Genesee BioMedical, Inc. considers the WellsForm™ Tricuspid Annuloplasty Band to be substantially equivalent to the predicate device. This conclusion is based upon the fact that devices have an equivalent intended use, and there are no clinical, technical, or biological differences in performance testing that raise new questions of safety and effectiveness.