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.