510(k) #: K250859

510(k) Summary

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Contact Details

21 CFR 807.92(a)(1)

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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.