

**K093903 ATS TRI-AD SEMI-FLEXIBLE TRICUSPID
ANUULOPLASTY, MODEL 900SFC**Jul 15, 2010
205 days to decisionK093903 · Product code: KRH · Cardiovascular
Source: <https://www.510kdatabase.net/k093903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ring, Annuloplasty (KRH)
Date received	Dec 22, 2009
Decision date	Jul 15, 2010
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genesee Biomedical, Inc.
Location	Denver, CO, US
Contact	JOHN T.M. WRIGHT
510(k) history	13 submissions · 13 cleared · 2005-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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