

K250859 TransForm McCarthy Mitral Annuloplasty Ring (TF)Jul 25, 2025
126 days to decisionK250859 · Product code: **KRH** · CardiovascularSource: <https://www.510kdatabase.net/k250859/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Mar 21, 2025
Decision date	Jul 25, 2025
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genesee Biomedical, Inc.
Location	Denver, CO, US
Contact	James Cross
510(k) history	13 submissions · 13 cleared · 2005-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250859/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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