

K190506 NeoForm Annuloplasty RingApr 18, 2019
48 days to decisionK190506 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k190506/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Mar 1, 2019
Decision date	Apr 18, 2019
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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