

**K161815 FlexForm Annuloplasty Ring and FlexForm Annuloplasty Band**

Oct 12, 2016  
103 days to decision

K161815 · Product code: **KRH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161815/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	Jul 1, 2016
Decision date	Oct 12, 2016
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k161815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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