

**K090428 ATS SIMULUS ADJUSTABLE FLEXIBLE  
ANNULOPLASTY, MODEL 735 AC**May 7, 2009  
77 days to decisionK090428 · Product code: **KRH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k090428/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Ring, Annuloplasty (KRH)           |
| Date received         | Feb 19, 2009                       |
| Decision date         | May 7, 2009                        |
| Days to decision      | 77 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Genesee Biomedical, Inc.</b>         |
| Location       | Denver, CO, US                          |
| Contact        | JOHN WRIGHT                             |
| 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/k090428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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