

**K110905 TOTAL SHOULDER SYSTEM**May 24, 2011  
54 days to decisionK110905 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k110905/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Mar 31, 2011
Decision date	May 24, 2011
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shoulder Innovations, LLC</b>
Location	Ada, MI, US
Contact	ANDREW RODENHOUSE
510(k) history	3 submissions · 3 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110905/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 18, 2026