

**K191811 Catalyst OrthoScience CSR Shoulder System**Sep 11, 2019  
68 days to decisionK191811 · Product code: **KWT** · Orthopedic  
Source: <https://www.510kdatabase.net/k191811/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Jul 5, 2019
Decision date	Sep 11, 2019
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Catalyst Orthoscience, Inc.</b>
Location	Naples, FL, US
Contact	Dale Davison
510(k) history	12 submissions · 12 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191811/> 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 26, 2026