

**K213349 Catalyst R1 Reverse Shoulder System**Jun 23, 2022  
258 days to decisionK213349 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k213349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Oct 8, 2021
Decision date	Jun 23, 2022
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	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/k213349/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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