

K252418 Catalyst F1x Shoulder SystemNov 6, 2025
97 days to decisionK252418 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k252418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Aug 1, 2025
Decision date	Nov 6, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252418/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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