

K234105 Catalyst F1x Shoulder SystemApr 5, 2024
101 days to decisionK234105 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k234105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 26, 2023
Decision date	Apr 5, 2024
Days to decision	101 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/k234105/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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