FDA 510(k) Premarket Notification

K234105 Catalyst F1x Shoulder System

CLEARED

Apr 5, 2024
101 days to decision

K234105 · 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