FDA 510(k) Premarket Notification

K213349 Catalyst R1 Reverse Shoulder System

CLEARED

Jun 23, 2022
258 days to decision

K213349 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k213349/

SUBMISSION DETAILS

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

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