

K223801 FX V135(TM) Shoulder ProsthesisJun 5, 2023
168 days to decisionK223801 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k223801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 19, 2022
Decision date	Jun 5, 2023
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fx Shoulder USA, Inc.
Location	Dallas, TX, US
Contact	Cory Trier
510(k) history	11 submissions · 11 cleared · 2019-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223801/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026