

**K213117 FX V135 Shoulder Prosthesis**Jun 7, 2022  
253 days to decisionK213117 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k213117/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 27, 2021
Decision date	Jun 7, 2022
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213117/> 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