

K222936 Humeris® 135 Shoulder SystemNov 7, 2022
42 days to decisionK222936 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k222936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 26, 2022
Decision date	Nov 7, 2022
Days to decision	42 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/k222936/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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