

**K193394 Humeral Cup Stability & Humeral Cup 135/145o
Stability**Apr 29, 2020
145 days to decisionK193394 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k193394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 6, 2019
Decision date	Apr 29, 2020
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193394/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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