FDA 510(k) Premarket Notification

# K223801 FX V135(TM) Shoulder Prosthesis

**CLEARED**

Jun 5, 2023
168 days to decision

K223801 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k223801/

## SUBMISSION DETAILS

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|---|---|
| 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 |