FDA 510(k) Premarket Notification

K213117 FX V135 Shoulder Prosthesis

CLEARED

Jun 7, 2022
253 days to decision

K213117 · 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	**Fx Shoulder USA, Inc.**
Location	Dallas, TX, US
Contact	Kathy Trier
510(k) history	11 submissions · 11 cleared · 2019-2024