FDA 510(k) Premarket Notification

K210790 Lateralized and Augmented Baseplates

CLEARED

Aug 25, 2021
162 days to decision

K210790 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k210790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Mar 16, 2021
Decision date	Aug 25, 2021
Days to decision	162 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