

K191146 Humelock TiN Coated GlenosphereJul 15, 2020
442 days to decisionK191146 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k191146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Apr 30, 2019
Decision date	Jul 15, 2020
Days to decision	442 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

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