

K191698 TiN Coated Humeral HeadJul 16, 2020
387 days to decisionK191698 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k191698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Jun 25, 2019
Decision date	Jul 16, 2020
Days to decision	387 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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