

K201391 Easytech® Anatomical Shoulder SystemFeb 16, 2021
265 days to decisionK201391 · Product code: **PKC** · Orthopedic
Source: <https://www.510kdatabase.net/k201391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	May 27, 2020
Decision date	Feb 16, 2021
Days to decision	265 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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