FDA 510(k) Premarket Notification

K211602 Klassic Knee System

CLEARED

Jul 23, 2021
60 days to decision

K211602 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k211602/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	May 24, 2021
Decision date	Jul 23, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Total Joint Orthopedics, Inc.**
Location	Sunnyvale, CA, US
Contact	Chris Weaber
510(k) history	21 submissions · 21 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Holly Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov