

K211877 Klassic Knee SystemJun 22, 2022
370 days to decisionK211877 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k211877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 17, 2021
Decision date	Jun 22, 2022
Days to decision	370 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	Macra, LLC
Contact	Holly Rhodes

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211877/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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