

K242984 BKS Revision SystemOct 25, 2024
29 days to decisionK242984 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k242984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 26, 2024
Decision date	Oct 25, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Development Corp.
Location	Draper, UT, US
Contact	Drew Weaver
510(k) history	45 submissions · 43 cleared · 1996-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242984/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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