

K230653 Smith & Nephew, Inc. ANTHEM Total Knee System, Genesis Uni Knee System, JOURNEY BCS and II Knee Systems, JOURNEY II CR Knee System, JOURNEY II Uni Knee System, Journey II UK Knee System, JOURNEY II XR Bi-Cruciate Retaining Knee System, JOURNEY PFJ System, JOURNEY Uni Knee System, Legion Hinge Total Knee System, Legion Total Knee System, ZUK Unicompartmental Knee System, ENGAGE Partial Knee System and Porous Patella and Porous Tibial Baseplates

May 4, 2023
56 days to decision

K230653 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k230653/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 9, 2023
Decision date	May 4, 2023
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	Tyler Kulcsar
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...