

K191211 JOURNEY II Unicompartmental Knee SystemJul 25, 2019
80 days to decisionK191211 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k191211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	May 6, 2019
Decision date	Jul 25, 2019
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	Meenakshi Gupta
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...