FDA 510(k) Premarket Notification

K120698 GENESIS II PS NON-MODULAR FEMORAL COMPONENT

CLEARED

May 18, 2012
72 days to decision

K120698 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k120698/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 7, 2012
Decision date	May 18, 2012
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	XIANG ZHANG
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...