# K121393 SMITH & NEPHEW, INC. TOTAL KNEE SYSTEM INSTRUMENTATION

**CLEARED**

Aug 7, 2012
90 days to decision

K121393 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k121393/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH) |
| Date received | May 9, 2012 |
| Decision date | Aug 7, 2012 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Smith & Nephew, Inc.** |
| Location | Mchenry, IL, US |
| Contact | GINO ROUSS |
| 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...