

**K113038 SMITH & NEPHEW INC. UNICOMPARTMENTAL AND  
BIOCOMPARTMENTAL KNEE SYSTEM INSTRUMENTS**Jan 5, 2012  
85 days to decisionK113038 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k113038/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX) |
| Date received         | Oct 12, 2011   |
| Decision date         | Jan 5, 2012  |
| Days to decision      | 85 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Smith &amp; Nephew, Inc.</b>   |
| Location       | Mchenry, IL, US   |
| Contact        | GINO ROUSS  |
| Website        | <a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a> |
| 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...