

K113848 R3 XLPE LINERSApr 27, 2012
120 days to decisionK113848 · Product code: **MBL** · Orthopedic
Source: <https://www.510kdatabase.net/k113848/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Uncemented, Metal/polymer, Porous (MBL) |
| Date received | Dec 29, 2011 |
| Decision date | Apr 27, 2012 |
| Days to decision | 120 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Smith & Nephew, Inc. |
| Location | Mchenry, IL, US |
| Contact | JOHN CONNOR |
| 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...