

K210566 LEGION Porous CR Narrow Femoral ComponentsMar 25, 2021
27 days to decisionK210566 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k210566/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH) |
| Date received | Feb 26, 2021 |
| Decision date | Mar 25, 2021 |
| Days to decision | 27 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Smith & Nephew, Inc. |
| Location | Mchenry, IL, US |
| Contact | Michelle Huettner |
| 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...

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Device record: <https://www.510kdatabase.net/k210566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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