

K003429 MALLOY/HEAD LATERALIZED PRESS-FIT FEMORALNov 30, 2000
27 days to decisionK003429 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k003429/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH) |
| Date received | Nov 3, 2000 |
| Decision date | Nov 30, 2000 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biomet, Inc. |
| Location | McHenry, IL, US |
| Contact | DALENE T BINKLEY |
| Website | http://www.biomet.com/ |
| 510(k) history | 440 submissions · 418 cleared · 1978-2024 |

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...