

**K912369 HAP BIO-GROOVE TOTAL HIP PROSTHESIS (BIO-COAT)**Oct 11, 1991  
135 days to decisionK912369 · Product code: **MEH** · Orthopedic  
Source: <https://www.510kdatabase.net/k912369/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH) |
| Date received         | May 29, 1991  |
| Decision date         | Oct 11, 1991  |
| Days to decision      | 135 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biomet, Inc.</b>   |
| Location       | Mchenry, IL, US   |
| Contact        | PATRICIA M SANDBORN   |
| Website        | <a href="http://www.biomet.com/">http://www.biomet.com/</a> |
| 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 ...