

**K914676 ZIMMER(R) CERAMIC FEMORAL HEADS 28MM  
DIAMETER**Jan 13, 1992  
87 days to decisionK914676 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k914676/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO) |
| Date received         | Oct 18, 1991   |
| Decision date         | Jan 13, 1992   |
| Days to decision      | 87 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Zimmer, Inc.</b>   |
| Location       | Warsaw, IN, US  |
| Contact        | ANGIE IDE   |
| Website        | <a href="https://www.zimmerbiomet.com">https://www.zimmerbiomet.com</a> |
| 510(k) history | 373 submissions · 352 cleared · 1976-2026                               |

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...