

K961378 DELTA HIP PROSTHESISOct 8, 1996
181 days to decisionK961378 · Product code: **LWJ** · Orthopedic
Source: <https://www.510kdatabase.net/k961378/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Uncemented (LWJ) |
| Date received | Apr 10, 1996 |
| Decision date | Oct 8, 1996 |
| Days to decision | 181 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Zimmer, Inc. |
| Location | Warsaw, IN, US |
| Contact | KAREN CAIN |
| Website | https://www.zimmerbiomet.com |
| 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 ...
