

**K982981 NEW ZIMMER SHOULDER SYSTEM**Dec 17, 1998  
113 days to decisionK982981 · Product code: **KWT** · Orthopedic  
Source: <https://www.510kdatabase.net/k982981/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                  |
| Submission type       | Traditional   |
| Device classification | Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT) |
| Date received         | Aug 26, 1998  |
| Decision date         | Dec 17, 1998  |
| Days to decision      | 113 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Zimmer, Inc.</b>   |
| Location       | Warsaw, IN, US  |
| Contact        | LAURA D WILLIAMS  |
| 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 ...

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