

**K010685 MODIFICATION TO MILLER/GALANTE PRECOAT UNICOMPARTMENTAL KNEE SYSTEM (8 MM ARTICULAR SURFACE)**Apr 2, 2001  
25 days to decisionK010685 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k010685/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Special  |
| Device classification | Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX) |
| Date received         | Mar 8, 2001  |
| Decision date         | Apr 2, 2001  |
| Days to decision      | 25 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Zimmer, Inc.</b>   |
| Location       | Warsaw, IN, US  |
| Contact        | STEPHEN H MCKELVEY  |
| 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 ...