

K823405 ZIMMER GREAT TOEJan 24, 1983
70 days to decisionK823405 · Product code: **KWH** · Orthopedic
Source: <https://www.510kdatabase.net/k823405/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Toe, Constrained, Polymer (KWH) |
| Date received | Nov 15, 1982 |
| Decision date | Jan 24, 1983 |
| Days to decision | 70 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Zimmer, Inc. |
| Location | Warsaw, IN, US |
| 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 ...