

K241651 Affixus Tibial and Antegrade Femoral Nailing SystemSep 26, 2024
111 days to decisionK241651 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k241651/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Jun 7, 2024 |
| Decision date | Sep 26, 2024 |
| Days to decision | 111 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Zimmer, Inc. |
| Location | Warsaw, IN, US |
| Contact | Akash Savalia |
| 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 ...