

K895198 HALL VERSIPOWER SURGICAL INSTRUMENT SYSTEMSep 15, 1989
35 days to decisionK895198 · Product code: **HWE** · Orthopedic
Source: <https://www.510kdatabase.net/k895198/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Surgical, Orthopedic, Ac-powered Motor And Accessory/attachment (HWE) |
| Date received | Aug 11, 1989 |
| Decision date | Sep 15, 1989 |
| Days to decision | 35 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Zimmer, Inc. |
| Location | Warsaw, IN, US |
| Contact | D WELLINGTON |
| 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 ...