

K946347 ABSORBABLE ACETABULAR SCREWJul 11, 1995
193 days to decisionK946347 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k946347/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Dec 30, 1994 |
| Decision date | Jul 11, 1995 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Zimmer, Inc. |
| Location | Warsaw, IN, US |
| Contact | LYNNETTE WHITAKER |
| 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 ...
