

K852137 FENLIN TOTAL SHOULDERFeb 12, 1986
272 days to decision

K852137 · Orthopedic

Source: <https://www.510kdatabase.net/k852137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	May 16, 1985
Decision date	Feb 12, 1986
Days to decision	272 days
Third-party review	No

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	MAX SHERMAN
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 ...