FDA 510(k) Premarket Notification

K834298 UNICONDYLAR FIBER METAL KNEE

CLEARED

Feb 13, 1984
67 days to decision

K834298 · Product code: **HRY** · Orthopedic
Source: https://www.510kdatabase.net/k834298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Dec 8, 1983
Decision date	Feb 13, 1984
Days to decision	67 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 ...