FDA 510(k) Premarket Notification

K830121 INSALL/BURSTEIN FIBER METAL CONDYLAR/KNE

CLEARED

Apr 26, 1983
105 days to decision

K830121 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k830121/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jan 11, 1983
Decision date	Apr 26, 1983
Days to decision	105 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 ...