FDA 510(k) Premarket Notification

K843219 ZIMMER BONE CEMENT CENTRIFUGATION SYS

CLEARED

Nov 29, 1984
106 days to decision

K843219 · Product code: **JDZ** · Orthopedic
Source: https://www.510kdatabase.net/k843219/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixer, Cement, For Clinical Use (JDZ)
Date received	Aug 15, 1984
Decision date	Nov 29, 1984
Days to decision	106 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 ...