FDA 510(k) Premarket Notification

K842343 SABA-COOMBS MINI EXTERNAL FIXATOR

CLEARED

Sep 11, 1984
89 days to decision

K842343 · Product code: **JEC** · Orthopedic
Source: https://www.510kdatabase.net/k842343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Component, Traction, Invasive (JEC)
Date received	Jun 14, 1984
Decision date	Sep 11, 1984
Days to decision	89 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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k842343/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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