FDA 510(k) Premarket Notification

CLEARED

K963431 POLYESTER PIL WRIST/ANKLE RESTRAINT/WRIST RESTRAINT UNIVERSAL/SOFT FLANNEL WRIST/ANKLE RESTRAINT/FOAM LIMB HOLDER

Nov 6, 1996
68 days to decision

K963431 · Product code: **FMQ** · General Hospital
Source: https://www.510kdatabase.net/k963431/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Restraint, Protective (FMQ)
Date received	Aug 30, 1996
Decision date	Nov 6, 1996
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	PAULA OSORIO
Website	https://www.zimmerbiomet.com
510(k) history	374 submissions · 353 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 ...