

**K942263 MILLER/GALANTE PRECOAT UNICOMPARTMENTAL
KNEE SYSTEM**Jul 11, 1995
428 days to decisionK942263 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k942263/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	May 9, 1994
Decision date	Jul 11, 1995
Days to decision	428 days
Third-party review	No

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	RUTH A WOOD
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 ...