

**K013385 NEXGEN COMPLETE KNEE SOLUTION ROTATING HINGE KNEE**Jan 9, 2002  
89 days to decisionK013385 · Product code: **KRO** · Orthopedic  
Source: <https://www.510kdatabase.net/k013385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Oct 12, 2001
Decision date	Jan 9, 2002
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer, Inc.</b>
Location	Warsaw, IN, US
Contact	STEPHEN MCKELVEY
Website	<a href="https://www.zimmerbiomet.com">https://www.zimmerbiomet.com</a>
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 ...