

**K043101 NEXGEN COMPLETE KNEE SOLUTION MIS TIBIAL COMPONENTS, LOCKING SCREW AND STEM EXTENSIONS**Mar 7, 2005  
118 days to decisionK043101 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k043101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Nov 9, 2004
Decision date	Mar 7, 2005
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer, Inc.</b>
Location	Warsaw, IN, US
Contact	BRANDON HIPSHER
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 ...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k043101/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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