

**K925635 TORUS EXTERNAL FIXATION SYSTEM**Jun 1, 1993  
204 days to decisionK925635 · Product code: **KTW** · Orthopedic  
Source: <https://www.510kdatabase.net/k925635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Single Component (KTW)
Date received	Nov 9, 1992
Decision date	Jun 1, 1993
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Zimmer, Inc.</b>
Location	Warsaw, IN, US
Contact	HENRY A QUELLO
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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