

K060704 ZIMMER TRABECULAR METAL REVERSE SHOULDER SYSTEM, SIZES 8MM AND 10MMMay 19, 2006
64 days to decisionK060704 · Product code: PHX · Orthopedic
Source: <https://www.510kdatabase.net/k060704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Mar 16, 2006
Decision date	May 19, 2006
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	DALENE T BINKLEY
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 ...

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Device record: <https://www.510kdatabase.net/k060704/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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