

# K991585 BIPOLAR SHOULDER PROSTHESIS

Aug 18, 1999  
103 days to decision

K991585 · Product code: **KWT** · Orthopedic  
Source: <https://www.510kdatabase.net/k991585/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	May 7, 1999
Decision date	Aug 18, 1999
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Biomet, Inc.</b>
Location	Mchenry, IL, US
Contact	FRED MCCLURE
Website	<a href="http://www.biomet.com/">http://www.biomet.com/</a>
510(k) history	440 submissions · 418 cleared · 1978-2024

Biomet, Inc. is an orthopedic medical device manufacturer based in McHenry, US. The company specializes in surgical implants, fixation systems, and trauma solutions. Biomet has maintained a strong FDA 510(k) regulatory record since its first clearance in 1978. The company has received FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio, reflecting the company's core focus on joint reconstruction, trauma fixation, and surgical instrumentation. The latest clearance in 2024 demonstrates continued regulatory activity and ...