

**K080642 COMPREHENSIVE REVERSE SHOULDER**Jul 9, 2008  
125 days to decisionK080642 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k080642/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Mar 6, 2008
Decision date	Jul 9, 2008
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet, Inc.</b>
Location	McHenry, IL, US
Contact	PATRICIA S BERES
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 ...

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