

**K003428 ISS OFFSET HEADS**Nov 24, 2000  
21 days to decisionK003428 · Product code: **HSD** · Orthopedic  
Source: <https://www.510kdatabase.net/k003428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	Nov 3, 2000
Decision date	Nov 24, 2000
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet, Inc.</b>
Location	Mchenry, IL, US
Contact	DALENE T BINKLEY
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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