

**K012378 3D HUMERAL HEADS**Dec 13, 2001  
140 days to decisionK012378 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k012378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jul 26, 2001
Decision date	Dec 13, 2001
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smith &amp; Nephew, Inc.</b>
Location	Mchenry, IL, US
Contact	DAVID HENLEY
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...

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