

**K033552 JAX-TCP**Jun 10, 2004  
211 days to decisionK033552 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k033552/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Nov 12, 2003
Decision date	Jun 10, 2004
Days to decision	211 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	KIM P KELLY
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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