

**K082381 GENEX**Nov 14, 2008  
87 days to decisionK082381 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k082381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Aug 19, 2008
Decision date	Nov 14, 2008
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocomposites, Ltd.</b>
Location	Keele, GB
Contact	SIMON FITZER
Website	<a href="https://www.biocomposites.com">https://www.biocomposites.com</a>
510(k) history	27 submissions · 27 cleared · 2000-2026

Biocomposites, Ltd. is an international medical device manufacturer based in Keele, GB. The company engineers and manufactures specialized devices for musculoskeletal infection, trauma, spine, and orthopedic applications. Biocomposites has received FDA 510(k) clearances from total submissions since 2000. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, confirming active regulatory engagement. The company's core product lines include antibiotic-loaded bone cem...

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