

**K003954 STIMULAN - CALCIUM SULFATE BONE VOID FILLER  
KIT**Jul 12, 2001  
203 days to decisionK003954 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k003954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Dec 21, 2000
Decision date	Jul 12, 2001
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocomposites, Ltd.</b>
Location	Keele, GB
Contact	J. STEPHEN BRATT
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...