

**K993238 FORTOSS-CEMA**Jan 14, 2000  
109 days to decisionK993238 · Product code: LYC · Dental  
Source: <https://www.510kdatabase.net/k993238/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Sep 27, 1999
Decision date	Jan 14, 2000
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocomposites, Ltd.</b>
Location	Keele, GB
Contact	JS 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...