FDA 510(k) Premarket Notification

K040600 GENEX BONE GRAFT SUBSTITUTE

CLEARED

May 7, 2004
60 days to decision

K040600 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k040600/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Mar 8, 2004
Decision date	May 7, 2004
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biocomposites, Ltd.**
Location	Keele, GB
Contact	J. STEPHEN BRATT
Website	https://www.biocomposites.com
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...