FDA 510(k) Premarket Notification

K212721 Genex Bone Graft Substitute

CLEARED

Feb 4, 2022
161 days to decision

K212721 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k212721/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Aug 27, 2021
Decision date	Feb 4, 2022
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biocomposites, Ltd.**
Location	Keele, GB
Contact	Simon Fitzer
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...