

K250521 NanoBone® SBX PuttyApr 7, 2025
45 days to decisionK250521 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k250521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 21, 2025
Decision date	Apr 7, 2025
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NanoBone® QD

APPLICANT

Company	Biocomposites, Ltd.
Location	Keele, GB
Contact	Ciara Airey
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...

REGULATORY CONSULTANT

Consulting firm	Bruder Consulting & Venture Group
Contact	Scott Bruder

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k250521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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