

K251522 Mg OSTEONJECT™Oct 13, 2025
150 days to decisionK251522 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k251522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	May 16, 2025
Decision date	Oct 13, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Mg OSTEOREVIVE™; Mg OSTEORETE™

APPLICANT

Company	Bone Solutions, Inc.
Location	Santa Barbara, CA, US
Contact	Drew Diaz
510(k) history	8 submissions · 8 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin Thomas

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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