

K212991 OsteoreviveJan 21, 2022
123 days to decisionK212991 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k212991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Sep 20, 2021
Decision date	Jan 21, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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 A Thomas

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212991/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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