

K250346 BonVie+Feb 26, 2025
20 days to decisionK250346 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k250346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 6, 2025
Decision date	Feb 26, 2025
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elute, Inc.
Location	Salt Lake City, UT, US
Contact	Ashok Khandkar
510(k) history	2 submissions · 2 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026