FDA 510(k) Premarket Notification

K250346 BonVie+

CLEARED

Feb 26, 2025
20 days to decision

K250346 · 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