

K250141 Synthecure Synthetic Calcium SulfateMay 16, 2025
119 days to decisionK250141 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k250141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jan 17, 2025
Decision date	May 16, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Austin Medical Ventures, Inc.
Location	Germantown, TN, US
Contact	Austin Brian
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J. Smith

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

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