FDA 510(k) Premarket Notification

K221256 Mg OSTEOINJECT

CLEARED

Jun 28, 2022
57 days to decision

K221256 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k221256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	May 2, 2022
Decision date	Jun 28, 2022
Days to decision	57 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