FDA 510(k) Premarket Notification

K210193 DB-Composite

K210193 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k210193/

CLEARED

Mar 15, 2021
49 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jan 25, 2021
Decision date	Mar 15, 2021
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dimensional Bioceramics, LLC**
Location	Scotts Valley, CA, US
Contact	Duran N. Yetkinliner
510(k) history	5 submissions · 5 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	**Trisler Consulting**
Contact	Patsy J. Trisler

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210193/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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