

K212353 DB-EZ Bone Void FillerSep 22, 2021
55 days to decisionK212353 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k212353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 29, 2021
Decision date	Sep 22, 2021
Days to decision	55 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

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