FDA 510(k) Premarket Notification

K171161 Dimensional Bioceramics Calcium Sulfate Device (DB-CSD)

CLEARED

Sep 25, 2017
158 days to decision

K171161 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k171161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Apr 20, 2017
Decision date	Sep 25, 2017
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k171161/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026