FDA 510(k) Premarket Notification

CLEARED

K231528 Bonalive Orthopedics granules

Jul 11, 2023
46 days to decision

K231528 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k231528/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	May 26, 2023
Decision date	Jul 11, 2023
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bonalive Biomaterials, Ltd.**
Location	Turku, FI
Contact	Kristoffer Sibelius
510(k) history	2 submissions · 2 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Obelix Consulting, LLC**
Contact	Elisa Maldonado-Holmertz

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/k231528/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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