

K240453 ReBOSSISMar 4, 2024
18 days to decisionK240453 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k240453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 15, 2024
Decision date	Mar 4, 2024
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthorebirth Co., Ltd.
Location	San Diego, CA, US
Contact	Yasutoshi Nishikawa
510(k) history	4 submissions · 4 cleared · 2014-2024

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Justin Eggleton

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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