

K233259 XerosynJun 21, 2024
266 days to decisionK233259 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k233259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Sep 29, 2023
Decision date	Jun 21, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xerothera, Inc.
Location	West Chester, PA, US
Contact	Noel Rolon
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Mehdi Kazemzadeh-Narbat

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/k233259/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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