FDA 510(k) Premarket Notification

K233259 Xerosyn

CLEARED

Jun 21, 2024
266 days to decision

K233259 · 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