FDA 510(k) Premarket Notification

K240450 Citrepore™

CLEARED

Nov 6, 2024
265 days to decision

K240450 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k240450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 15, 2024
Decision date	Nov 6, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acuitive Technologies, Inc.**
Location	Alendale, NJ, US
Contact	Matthew Poggie
510(k) history	6 submissions · 6 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert Poggie

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