FDA 510(k) Premarket Notification

K250556 Porous Biologic Scaffold

CLEARED

Mar 21, 2025
24 days to decision

K250556 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k250556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 25, 2025
Decision date	Mar 21, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ventris Medical**
Location	Newport Beach, CA, US
Contact	John Brunelle
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Bruder Consulting & Venture Group**
Contact	Scott Bruder

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