FDA 510(k) Premarket Notification

K231968 Tactoset® Injectable Bone Substitute

CLEARED

Dec 20, 2023
170 days to decision

K231968 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k231968/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 3, 2023
Decision date	Dec 20, 2023
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anika Therapeutics, Inc.**
Location	Beford, MA, US
Contact	Wei Zhao
Website	http://www.anikatherapeutics.com/
510(k) history	9 submissions · 9 cleared · 2017-2025

Anika Therapeutics, Inc. is a global leader in hyaluronic acid-based orthopedic regenerative solutions and osteoarthritis pain management. The company develops advanced tissue repair, cartilage regeneration, and injectable bone substitute technologies with a manufacturing facility in Bedford, US. Anika has received FDA 510(k) clearances from total submissions since 2017. Orthopedic devices represent the dominant focus of the company's regulatory portfolio. The latest clearance was received in 2025, reflecting active ongoing innovation and market engagement. The company's ...

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Mehdi Kazemzadeh-Narbat

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