

**K212083 Tactoset Injectable Bone Substitute**Aug 31, 2021  
60 days to decisionK212083 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k212083/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 2, 2021
Decision date	Aug 31, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anika Therapeutics, Inc.</b>
Location	Beford, MA, US
Contact	Wei Zhao
Website	<a href="http://www.anikatherapeutics.com/">http://www.anikatherapeutics.com/</a>
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**

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Consulting firm	<b>Musculoskeletal Clinical Regulatory Advisers, LLC</b>
Contact	Wei Zhao

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k212083/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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