

**K231641 Rotium Bioresorbable Wick**Jul 5, 2023  
30 days to decisionK231641 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k231641/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jun 5, 2023
Decision date	Jul 5, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanofiber Solutions, LLC</b>
Location	Hilliard, OH, US
Contact	Jason Chakroff
510(k) history	5 submissions · 5 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231641/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026