

**K250021 Rotium**Feb 27, 2025  
55 days to decisionK250021 · Product code: **OWW** · Orthopedic  
Source: <https://www.510kdatabase.net/k250021/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon (OWW)
Date received	Jan 3, 2025
Decision date	Feb 27, 2025
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	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/k250021/> 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 14, 2026