

**K251224 Restrata Soft Tissue Reinforcement (STR)**Jun 20, 2025  
60 days to decisionK251224 · Product code: **OXF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251224/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Plastic And Reconstructive Surgery (OXF)
Date received	Apr 21, 2025
Decision date	Jun 20, 2025
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>Acera Surgical, Inc.</b>
Location	St. Louis, MO, US
Contact	Tamas Kovacs
510(k) history	7 submissions · 7 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251224/> 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 13, 2026