

**K193583 Restrata®**Sep 25, 2020  
277 days to decisionK193583 · Product code: **QSZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Absorbable Synthetic Wound Dressing (QSZ)
Date received	Dec 23, 2019
Decision date	Sep 25, 2020
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acera Surgical, Inc.</b>
Location	St. Louis, MO, US
Contact	Lily Jeng
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/k193583/> 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 26, 2026