

**K251567 NovoSorb BTM**Jun 20, 2025  
29 days to decisionK251567 · Product code: **QSZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251567/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Absorbable Synthetic Wound Dressing (QSZ)
Date received	May 22, 2025
Decision date	Jun 20, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Polynovo Biomaterials Pty, Ltd.</b>
Location	Austin, TX, US
Contact	Shruti Dave
510(k) history	6 submissions · 6 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251567/> 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